AUTHORITY: section 190.618, RSMo Supp. 2008. Original rule filed Jan. 9, 2009, effective Aug. 30, 2009.*

**Original authority: 190.618, RSMo 2007.*

19 CSR 30-40.710 Definitions and Abbreviations Relating to Stroke Centers

PURPOSE: This rule defines terminology related to stroke centers.

(1) As used in 19 CSR 30-40.720 and 19 CSR 30-40.730, the following terms shall mean:

(A) Acute—an injury or illness that happens or appears quickly and can be serious or life threatening;

(B) Anesthesiologist assistant (AA)—a person who—

1. Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

5. Provides health care services delegated by a licensed anesthesiologist;

(C) Board-admissible/board-eligible—a physician who is eligible to apply or has applied to a specialty board of the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada and has received a ruling that he or she has fulfilled the requirements to take the examinations. Board certification is generally obtained within five (5) years of the first appointment;

(D) Board-certified—a physician who has fulfilled all requirements, has satisfactorily completed the written and oral examinations, and has been awarded a board diploma in a specialty field by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada;

(E) Catchment area—the surrounding area served by the institution (the stroke center);

(F) Certified registered nurse anesthetist (CRNA)—a registered nurse who—

1. Has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Education Programs of Nurse Anesthesia or its predecessor;

2. Has been certified as a nurse anesthetist by the Council on Certification of Nurse Anesthetists; and

3. Has been licensed in Missouri pursuant to Chapter 335, RSMo;

(G) Clinical staff—an individual that has specific training and experience in the treatment and management of stroke patients. Examples include: physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists;

(H) Clinical team—a team of healthcare professionals involved in the care of the stroke patient and may include, but not be limited to, neurologists, neuro-interventionalists, neurosurgeons, anesthesiologists, emergency medicine, and other stroke center clinical staff. The clinical team is part of the hospital program's stroke team;

(I) Continuing education—education approved or recognized by a national and/or state professional organization and/or stroke medical director;

(J) Continuing medical education (CME)—the highest level of continuing education for physicians that is approved or recognized by a national and/or state professional organization and/or stroke medical director;

(K) Core team—a subunit of the hospital stroke team consisting of a physician experienced in diagnosing and treating cerebrovascular disease (usually the stroke medical director) and at least one (1) other health care professional or qualified individual competent in stroke care as determined by the hospital (usually the stroke program manager/coordinator);

(L) Credentialed or credentialing—a hospital-specific system of documenting and recognizing the qualifications of medical staff and nurses and authorizing the performance of certain procedures and establishing clinical privileges in the hospital setting;

(M) Department—the Missouri Department of Health and Senior Services;

(N) Door-to-needle time—the time from arrival at the hospital door to initiation of lytic therapy to restore blood flow in an obstructed blood vessel;

(O) Emergency medical service regions—the six (6) regions in the state of Missouri that are defined in 19 CSR 30-40.302;

(P) Hospital—an establishment as defined by section 197.020.2, RSMo, or a hospital operated by the state;

(Q) Immediately available (IA)—being present at the bedside at the time of the patient's arrival at the hospital when prior notification is possible and no more than twenty (20) minutes from the hospital under normal driving and weather conditions;

(R) In-house (IH)—being on the hospital premises twenty-four (24) hours a day;

(S) Lytic therapy (also known as fibrinolysis/thrombolysis)—a drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(T) Missouri stroke registry—a statewide data collection system comprised of key data elements as defined in 19 CSR 30-40.730 that are used to compile and trend statistics of stroke patients in both pre-hospital and hospital settings, using a coordinated electronic reporting method provided by the department;

(U) Multidisciplinary team—a team of appropriate representatives of hospital units involved in the care of the stroke patient. This team supports the care of the stroke patient with the stroke team;

(V) Neurologist—a licensed physician with the appropriate specialty training;

(W) Neuro-interventionalist—a licensed physician with the appropriate specialty training;

(X) Neuro-interventional team—a team of physicians, nurses, and other clinical staff, and technical support that perform the neuro-interventions and who are part of the stroke clinical team;

(Y) Neurology service—an organizational component of the hospital specializing in the care of patients who have had strokes or some other neurological condition or disorder;

(Z) Patient—an individual who is sick, injured, wounded, diseased, or otherwise incapacitated or helpless, or dead, excluding deceased individuals being transported from or between private or public institutions, homes, or cemeteries, and individuals declared dead prior to the time an ambulance is called for assistance;

(AA) Peer review system—the process the stroke center establishes for physicians to review stroke cases on patients who are admitted to the stroke center, transferred out of the stroke center, or die as a result of the stroke (independent of hospital admission or hospital transfer status);

(BB) Physician—a person licensed as a physician pursuant to Chapter 334, RSMo;

(CC) Promptly available (PA)—arrival at the hospital at the patient's bedside within thirty (30) minutes after notification of a patient's arrival at the hospital;

(DD) Protocol—a predetermined, written medical care guideline, which may include standing orders;

(EE) Qualified individual—a physician, registered nurse, advanced practice nurse, and/or physician assistant licensed in the state of Missouri who demonstrates administrative ability and shows evidence of educational and clinical experience in the care of cerebrovascular patients;

(FF) Regional outcome data—data used to assess the regional process for pre-hospital, hospital, and regional patient outcomes;

(GG) Repatriation—the process used to return a stroke patient to his or her home community from a level I or level II stroke center after his or her acute treatment for stroke has been completed. This allows the patient to be closer to home for continued hospitalization or rehabilitation and follow-up care as indicated by the patient's condition;

(HH) Reperfusion—the process of restoring normal blood flow to an organ or tissue that has had its blood supply cut off, such as after an ischemic stroke or myocardial infarction;

(II) Requirement (R)—a symbol used to indicate that a standard is a requirement for stroke center designation at a particular level;

(JJ) Review—the inspection of a hospital to determine compliance with the rules of this chapter;

(KK) Stroke—a sudden brain dysfunction due to a disturbance of cerebral circulation. The resulting impairments include, but are not limited to, paralysis, slurred speech, and/or vision loss. Ischemic strokes are typically caused by the obstruction of a cerebral blood vessel. Hemorrhagic strokes are typically caused by rupture of a cerebral artery;

(LL) Stroke call roster—a schedule that provides twenty-four (24) hours a day, seven (7) days a week neurology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of the stroke patients;

(MM) Stroke care—emergency transport, triage and acute intervention, and other acute care services for strokes that potentially require immediate medical or surgical intervention or treatment, and may include education, primary prevention, acute intervention, acute and sub-acute management, prevention of complications, secondary stroke prevention, and rehabilitative services;

(NN) Stroke center—a hospital that is currently designated as such by the department to care for patients with a stroke.

1. A level I stroke center is a receiving center staffed and equipped to provide total care for every aspect of stroke care, including care for those patients with complications, that also functions as a resource center for the hospitals within that region, and conducts research.

2. A level II stroke center is a receiving center staffed and equipped to provide care for a large number of stroke patients within the region.

3. A level III stroke center is a referral center staffed and equipped to initiate lytic therapy and initiate timely transfer to a higher level of care. The level III stroke center also provides prompt assessment, indicated resuscitation, and appropriate emergency intervention for stroke patients. A level III stroke center may admit and monitor patients as in-patients if there are designated stroke beds and an established relationship exists with a level I or level II stroke center through which the level I or level II stroke center provides medical direction and oversight for those stroke patients kept at the level III stroke center under that relationship.

4. A level IV stroke center is a referral center in an area considered rural or where there are insufficient hospital resources to serve the patient population requiring stroke care. A level IV stroke center provides prompt assessment, indicated resuscitation, appropriate emergency intervention, and arranges and expedites transfer to a higher level stroke center as needed;

(OO) Stroke medical director—a physician designated by the hospital who is responsible for the stroke service and performance improvement and patient safety programs related to stroke care;

(PP) Stroke program—an organizational component of the hospital specializing in the care of stroke patients;

(QQ) Stroke program manager/coordinator—a qualified individual designated by the hospital with responsibility for monitoring and evaluating the care of stroke patients and the coordination of performance improvement and patient safety programs for the stroke center in conjunction with the stroke medical director;

(RR) Stroke team—a component of the hospital stroke program consisting of the core stroke team and the clinical stroke team;

(SS) Stroke unit—the functional division or facility of the hospital that provides care for stroke patients admitted to the stroke center;

(TT) Symptom onset-to-treatment time—the time from symptom onset to initiation of therapy to restore blood flow in an obstructed blood vessel;

(UU) Telemedicine—the use of medical information exchanged from one (1) site to another via electronic communications to improve patient's health status. A neurology specialist will assist the physician in the center in rendering a diagnosis. This may involve a patient "seeing" a specialist over a live, remote consult or the transmission of diagnostic images and/or video along with patient data to the specialist;

(VV) Thrombolytics—drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction; and

(WW) Transfer agreement—a document which sets forth the rights and responsibilities of two (2) hospitals regarding the inter-hospital transfer of patients.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.720 Stroke Center Designation Application and Review

PURPOSE: This rule establishes the requirements for participation in Missouri's stroke center program.

(1) Participation in Missouri's stroke center program is voluntary and no hospital shall be required to participate. No hospital shall hold itself out to the public as a state-designated stroke center unless it is designated as such by the Department of Health and Senior Services (department). Hospitals desiring stroke center designation shall apply to the department. Only those hospitals found by review to be in compliance with the requirements of the rules of this chapter shall be designated by the department as stroke centers.

(A) An application for stroke center designation shall be made upon forms prepared or prescribed by the department and shall contain information the department deems necessary to make a fair determination of eligibility for review and designation in accordance with the rules of this chapter. The stroke center review and designation application form, included herein, is available at the Health Standards and Licensure (HSL) office, or online at the department's website at www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570. The application for stroke center designation shall be submitted to the department no less than sixty (60) days and

no more than one hundred twenty (120) days prior to the desired date of the initial designation or expiration of the current designation.

(B) Both sections A and B of the stroke center review and designation application form, included herein, shall be complete before the department will arrange a date for the review. The department shall notify the hospital/stroke center of any apparent omissions or errors in the completion of the stroke center review and designation application form. When the stroke center review and designation application form is complete, the department shall contact the hospital/stroke center to arrange a date for the review.

(C) The hospital/stroke center shall cooperate with the department in arranging for a mutually suitable date for any announced reviews.

(D) The hospital/stroke center may request any announced initial and validation reviews by the department be coordinated with the hospital's/stroke center's Joint Commission Stroke Center Survey, if applicable. The department may grant such a request to the extent practical.

(2) The different types of site reviews to be conducted on hospitals/stroke centers seeking stroke center designation include:

(A) An initial review shall occur on a hospital applying to be initially designated as a stroke center. An initial review shall include interviews with designated hospital staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter;

(B) A validation review shall occur on a designated stroke center applying for renewal of its designation as a stroke center. Validation reviews shall occur no less than every four (4) years. A validation review shall include interviews with designated stroke center staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter; and

(C) A focus review shall occur on a designated stroke center in which a validation review was conducted and substantial deficiency(ies) were cited. A review of the physical plant will not be necessary unless a deficiency(ies) was cited in the physical plant in the preceding validation review. The focus review team shall be comprised of a representative from the department and may include a qualified contractor(s) with the required expertise to evaluate corrections in areas where deficiencies were cited.

(3) Stroke center designation shall be valid for a period of four (4) years from the date the stroke center/hospital is designated.

(A) Stroke center designation shall be site specific and non-transferable when a stroke center changes location.

(B) Once designated as a stroke center, a stroke center may voluntarily surrender the designation at any time without giving cause, by contacting the department in writing. In these cases, the application and review process shall be completed again before the designation may be reinstated.

(4) For the purpose of reviewing previously designated stroke centers and hospitals applying for stroke center designation, the department shall use review teams consisting of qualified contractors. These review teams shall consist of one (1) stroke coordinator or stroke program manager who has experience in stroke care and one (1) emergency medicine physician also experienced in stroke care. The review team shall also consist of at least one (1) and no more than two (2) neurologist(s)/neuro-interventionalist(s) who are experts in stroke care. One (1) representative from the department will also be a participant of the review team. This representative shall coordinate the review with the hospital/stroke center and the other review team members. For a hospital applying to the department as a level I stroke center for an initial review and which provides the department with verification of certification by the Joint Commission as a Comprehensive Stroke Center, the review team shall consist of at least one (1) representative from the department and may also include one (1) qualified contractor. For a hospital applying to the department as a level II stroke center for an initial review and which provides the department with verification of certification by the Joint Commission as a Primary Stroke Center, the review team shall consist of at least one (1) representative from the department and may also include one (1) qualified contractor.

(A) Any individual interested in becoming a qualified contractor to conduct reviews shall—

1. Send the department a curriculum vitae (CV) or resume that includes his or her experience and expertise in stroke care and whether an individual is in good standing with his or her licensing boards. A qualified contractor shall be in good standing with his or her respective licensing boards;

2. Provide the department evidence of his or her previous site survey experience (state and/or national designation survey process); and

3. Submit a list to the department that details any ownership he or she may have in a Missouri hospital(s), whether he or she has been terminated from any Missouri hospital(s), any lawsuits he or she has currently or had in the past with any Missouri hospital(s), and any Missouri hospital(s) for which his or her hospital privileges have been revoked.

(B) Qualified contractors for the department shall enter into a written agreement with the department indicating, that among other things, they agree to abide by Chapter 190, RSMo, and the rules in this chapter, during the review process.

(5) Out-of-state review team members shall conduct levels I and II hospital/stroke center reviews. Review team members are considered out-of-state review team members if they work outside of the state of Missouri. In-state review team members may conduct levels III and IV hospital/stroke center reviews. Review team members are considered in-state review team members if they work in the state of Missouri. In the event that out-of-state reviewers are unavailable, levels I and II stroke center reviews may be conducted by in-state reviewers from Emergency Medical Services (EMS) regions as set forth in 19 CSR 30-40.302 other than the region being reviewed with the approval of the director of the department or his/her designee. When utilizing in-state review teams, levels I and II hospital/stroke centers shall have the right to refuse one (1) in-state review team or certain members from one (1) in-state review team.

(6) Hospitals/stroke centers shall be responsible for paying expenses related to the cost of the qualified contractors to review their respective hospitals/stroke centers during initial, validation, and focus reviews. The department shall be responsible for paying the expenses of its representative. Costs of the review to be paid by the hospital/stroke center include:

(A) An honorarium shall be paid to each qualified contractor of the review team. Qualified contractors of the review team for level I and II stroke center reviews shall be paid six hundred dollars ($600) for the day of travel per reviewer and eight hundred fifty dollars ($850) for the day of the review per reviewer. Qualified contractors of the review team for level III and IV stroke center reviews shall be paid five hundred dollars ($500) for the day of travel per reviewer and five hundred dollars ($500) for the day of the review per reviewer. This honorarium shall be paid to each qualified contractor of the review team at the time the site survey begins;

(B) Airfare shall be paid for each qualified contractor of the review team, if applicable;

(C) Lodging shall be paid for each qualified contractor of the review team. The hospital/stroke center shall secure the appropriate number of hotel rooms for the qualified contractors and pay the hotel directly; and

(D) Incidental expenses, if applicable, for each qualified contractor of the review team shall not exceed two hundred fifty dollars ($250) and may include the following:

1. Airport parking;
2. Checking bag charges;
3. Meals during the review; and
4. Mileage to and from the review if no airfare was charged by the reviewer. Mileage shall be paid at the federal mileage rate for business miles as set by the Internal Revenue Service (IRS). Federal mileage rates can be found at the website www.irs.gov.

(7) Upon completion of a review, the qualified contractors from the review team shall submit a report of their findings to the department. This report shall state whether the specific standards for stroke center designation have or have not been met and if not met, in what way they were not met. This report shall detail the hospital/stroke center's strengths, weaknesses, deficiencies, and recommendations for areas of improvement. This report shall also include findings from patient chart audits and a narrative summary of the following areas: prehospital, hospital, stroke service, emergency department, operating room, angiography suites, recovery room, clinical lab, intensive care unit, rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review, and interviews. The department shall have the final authority to determine compliance with the rules of this chapter.

(8) The department shall return a copy of the report to the chief executive officer, the stroke medical director, and the stroke program manager/coordinator of the hospital/stroke center reviewed. Included within the report shall be notification indicating whether the hospital/stroke center has met the criteria for stroke center designation or has failed to meet the criteria for the stroke center designation requested. Also, if a focus review of the stroke center is required, the time frame for this focus review will be shared with the chief executive officer, the stroke medical director, and the stroke program manager/coordinator of the stroke center reviewed.

(9) When the hospital/stroke center is found to have deficiencies, the hospital/stroke center shall submit a plan of correction to the department. The plan of correction shall include identified deficiencies, actions to be taken to correct deficiencies, time frame in which the deficiencies are expected to be resolved, and the person responsible for the actions to resolve the deficiencies. A plan of correction form shall be completed by the hospital and returned to the department within thirty (30) days after notification of review findings and designation. If a focus review is required, then the stroke center shall be allowed a minimum period of six (6) months to correct deficiencies.

(10) A stroke center shall make the department aware in writing within thirty (30) days if there are any changes in the stroke center's name, address, contact information, chief executive officer, stroke medical director, or stroke program manager/coordinator.

(11) Any person aggrieved by an action of the Department of Health and Senior Services affecting the stroke center designation pursuant to Chapter 190, RSMo, including the revocation, the suspension, or the granting of, refusal to grant, or failure to renew a designation, may seek a determination thereon by the Administrative Hearing Commission under Chapter 621, RSMo. It shall not be a condition to such determination that the person aggrieved seek reconsideration, a rehearing, or exhaust any other procedure within the department.

(12) The department may deny, place on probation, suspend, or revoke such designation in any case in which it has reasonable cause to believe that there has been a substantial failure to comply with the provisions of Chapter 190, RSMo, or any rules or regulations promulgated pursuant to this chapter. If the Department of Health and Senior Services has reasonable cause to believe that a hospital is not in compliance with such provisions or regulations, it may conduct additional announced or unannounced site reviews of the hospital to verify compliance. If a stroke center fails two (2) consecutive onsite reviews because of substantial noncompliance with standards prescribed by sections 190.001 to 190.245, RSMo, or rules adopted by the department pursuant to sections 190.001 to 190.245, RSMo, its center designation shall be revoked.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STROKE CENTER REVIEW AND DESIGNATION

SECTION A

In accordance with the requirements of the Chapter 190 RSMo and the applicable regulations, this application is hereby submitted for review and designation as a stroke center. Please complete all information applicable to the requested designation level.	Designation Level Requested ☐ I ☐ II ☐ III ☐ IV

Joint Commission Certification
☐ Primary Stroke Center ☐ Comprehensive Stroke Center

HOSPITAL INFORMATION

Name Of Hospital (Name To Appear On Designation Certificate)	Telephone Number
Address (Street And Number)	City / Zip Code

PROFESSIONAL INFORMATION

Chief Executive Officer	Chairman/President Of Board Of Trustees
Stroke Medical Director	Stroke Program Manager
Medical Director of Emergency Medicine	Medical Director of Intensive Care Unit

RESOURCE INFORMATION

Stroke Caseload	Stroke Team Activations	CT Scan Capability ☐ FULL ☐ PARTIAL ☐ NONE	MRI Capability ☐ FULL ☐ PARTIAL ☐ NONE
Neurosurgical Capability or Transfer Plan	ICU or NICU Beds	Stroke Unit Beds	Stroke Rehab ☐ INPATIENT ☐ OUTPATIENT
Neurologists	Neurosurgeons	Neuro-Interventionalists	Emergency Department (ED) Physicians
Anesthesiologists/ CRNAs & AAs	Angiography Suites	Avg number of patients who received neuro-intervention (not required for initial review)	Avg number of patients who received thrombolytics in the past 24 months (not required for initial review)

CERTIFICATION

We, the undersigned, hereby certify that the information provided in this application for stroke center review and designation is true and accurate; and give assurance of the intent and ability of the hospital to comply with regulations promulgated under the Chapter 190, RSMo.

We further certify that the hospital will comply with all recommendations for improvement contained in the stroke center site review reports prepared by the Missouri Department of Health and Senior Services.

Date of application_____

Signed_____
Chairman/President of Board of Trustees, Owner, or one Partner of Partnership

Signed_____
Hospital Chief Executive Officer

Signed_____
Stroke Medical Director

Signed_____
Director of Emergency Medicine

MO 580 EMS

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STROKE CENTER REVIEW AND DESIGNATION

SECTION B

Please attach the following documentation to the application form. **Name of Hospital:**

- ☐ Hospital organizational chart depicting the relationship of the stroke services to other services and defining the organizational structure of the stroke service.
- ☐ Job descriptions and CV for the stroke medical director and stroke coordinator/program manager.
- ☐ A narrative description of the administrative commitment for the stroke center, including how stroke center designation relates to the overall mission of the hospital.
- ☐ A current board resolution supporting the stroke center.
- ☐ A narrative description of the catchment area for the stroke center.
- ☐ A narrative description of the prehospital system including the hospital's participation in medical control, quality assurance, and education of the emergency medicine personnel.
- ☐ Hospital diversion policy.
- ☐ List of the stroke medical director and stroke program coordinator or program manager (core stroke team) indicating the neuro-cerebrovascular related continuing education for each over the past three (3) years. (Do not send continuing education information about the clinical stroke team. This should be available at the time of the review.)
- ☐ Multidisciplinary team policy.
- ☐ List of all neurologists, neurosurgeons, neuro-interventionalists and emergency department physicians and indicate stroke-related CME for each over the past three (3) years.
- ☐ List of physicians and plan for supervised relationship between Level III and higher level stroke center where stroke patients are admitted for care in a Level III center if applicable (this list and plan are only required for Level III centers with a supervised relationship with a Level I or Level II center).
- ☐ Narrative description of the system for notifying/activating stroke team.
- ☐ One-call stroke team activation protocol.
- ☐ Copies of all transfer agreements pertaining to stroke.
- ☐ Policy for consultation for physical medicine and rehabilitation, physical therapy, occupational therapy and speech therapy.
- ☐ Protocols on post-discharge and post-transfer follow-up for stroke patients.
- ☐ A narrative description of the stroke quality improvement (QI) processes utilized by the hospital (Do not send copies of QI minutes or documents. These should be available at the time of review.)
- ☐ Examples of stroke-related educational, outreach, and research projects undertaken by the hospital.
- ☐ Summary of source of stroke information for Table 1 on next page. Table 1 is only required to be filled out by a stroke center which is applying for renewal of its designation prior to a validation review. Table 1 is not required to be filled out by a hospital requesting an initial review and designation.
- ☐ Verification of Primary or Comprehensive Joint Commission certified center (e.g. certificate).

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STROKE CENTER REVIEW AND DESIGNATION

Table 1. Ischemic Stroke Numbers for Past Two (2) Years

Table 1 is only required to be filled out by a stroke center which is applying for renewal of its designation prior to a validation review.

A	B	C	D	E
Indicate year[1] Provide two years of data	Stroke cases[2] / Transfers[3]	Stroke cases eligible for NI[4] / Received NI[5]	Stroke cases eligible for Lytics[6] / Received lytics[7]	Stroke deaths[8]
For example: 2011	53 / 22	14 / 8	25 / 12	2
Total				
Average/Year				

[1] Include data for the last two (2) years of hospital data. Indicate time frame in months if it is other than January to December.
[2] Include all stroke patients, independent of hospital admission or hospital transfer status. To include walk-ins, transfers, EMS transports, admitted patients, and patients that die. Include all stroke patients that have ICD-9-principal diagnosis code of 433.01, 433.10, 433.11, 433.21, 433.31, 433.81, 433.91, 434.00, 434.01, 434.11, 434.91, 436.00, 430.00 and 431.00
[3] Provide number of all stroke patients transferred to this hospital from another hospital.
[4] Provide number of stroke patients eligible for neuro-intervention (NI).
[5] Provide number of stroke patients that received neuro-intervention (NI).
[6] Provide number of stroke patients that are eligible for thrombolytics.
[7] Provide number of stroke patients that received thrombolytics.
[8] Include all deaths, ED and inpatient, independent of hospital admission or hospital transfer status.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.730 Standards for Stroke Center Designation

PURPOSE: This rule establishes standards for level I, II, III, and IV stroke center designation.

AGENCY NOTE:
I-R, II-R, III-R, or IV-R after a standard indicates a requirement for level I, II, III, or IV stroke centers respectively.
I-IH, II-IH, III-IH, or IV-IH after a standard indicates an in-house requirement for level I, II, III, or IV stroke centers respectively.
I-IA, II-IA, III-IA, or IV-IA indicates an immediately available requirement for level I, II, III, or IV stroke centers respectively.
I-PA, II-PA, III-PA, or IV-PA indicates a promptly available requirement for level I, II, III, or IV stroke centers respectively.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for Stroke Center Designation.

(A) The stroke center board of directors, administration, medical staff, and nursing staff shall demonstrate a commitment to quality stroke care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a stroke center; assure that all stroke patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human, and physical resources as needed for the stroke program; and establish a priority admission for the stroke patient to the full services of the institution. (I-R, II-R, III-R, IV-R)

(B) Stroke centers shall agree to accept all stroke patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed, or ability to pay. (I-R, II-R, III-R, IV-R)

(C) The stroke center shall demonstrate evidence of a stroke program. The stroke program shall be available twenty-four (24) hours a day, seven (7) days a week to evaluate and treat stroke patients. (I-R, II-R, III-R, IV-R)

1. The stroke center shall maintain a stroke team that at a minimum shall consist of—

A. A core team which provides administrative oversight and includes:

(I) A physician experienced in diagnosing and treating cerebrovascular disease (usually the stroke medical director); and (I-R, II-R, III-R, IV-R)

(II) At least one (1) other health care professional or qualified individual credentialed in stroke patient care (usually the stroke program manager/coordinator); (I-R, II-R, III-R, IV-R)

B. A stroke call roster that provides twenty-four (24) hours a day, seven (7) days a week neurology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of stroke patients. A level I stroke center call roster shall include, but not be limited to, the emergency department physician, neuro-interventionalist, neurologist, and others as appropriate. A level II stroke center call roster shall include, but not be limited to, the emergency department physician, a physician with experience and expertise in diagnosing and treating patients with cerebrovascular disease, and others as appropriate. The level III stroke center call roster shall include, but not be limited to, the emergency department physician and others as appropriate. A level IV stroke center call roster shall include, but not be limited to, the emergency department physician and other qualified individuals as appropriate. (I-R, II-R, III-R, IV-R)

(I) This coverage shall be available from notification of stroke patients according to the response requirements as set out below—

(a) Level I and II stroke centers shall have this coverage available within fifteen (15) minutes of notification of a stroke patient; and (I-R, II-R)

(b) Level III and IV stroke centers shall have a regional networking agreement with a level I or level II stroke center for telephone consult or telemedicine consultation available within fifteen (15) minutes of notification of a stroke patient; and (III-R, IV-R)

C. A clinical team appropriate to the center level designation that may include, but not be limited to, members of the stroke call roster, neurologists, physicians with expertise caring for stroke patients, neuro-interventionalists, neurosurgeons, anesthesiologists, intensivists, emergency department physicians, and other stroke center clinical staff as applicable. (I-R, II-R, III-R, IV-R)

2. The stroke center shall have a peer review system to review stroke cases respective of the stroke center's designation. (I-R, II-R, III-R, IV-R)

3. The stroke team members shall have appropriate experience to maintain skills and proficiencies to care for stroke patients. The stroke center shall maintain evidence that it meets the following requirements by documenting the following:

A. A list of all stroke team members; (I-R, II-R, III-R, IV-R)

B. Position qualifications and completion of continuing education requirements by stroke team members as set forth in sections (1), (2), and (4) of this rule; (I-R, II-R, III-R, IV-R)

C. Management of sufficient numbers of stroke patients by the stroke team members in order to maintain their stroke skills; (I-R, II-R, III-R, IV-R)

D. Participation by the core team and members of the stroke call roster in at least half of the regular, ongoing stroke program peer review system meetings as shown in meeting attendance documents. The stroke medical director shall disseminate the information and findings from the peer review system meetings to the stroke call roster members and the core team and document such dissemination; (I-R, II-R, III-R, IV-R)

E. Participation by stroke team members in at least half of the regular, ongoing stroke program performance improvement and patient safety meetings and documentation of such attendance in the meeting minutes and/or meeting attendance documents. The stroke medical director shall disseminate the information and findings from the performance improvement and patient safety meetings to the stroke team members and document such dissemination. If a stroke team member is unable to attend a stroke program performance improvement and patient safety meeting, then the stroke team member shall send an appropriate representative in his/her place; (I-R, II-R, III-R, IV-R)

F. Maintenance of skill levels in the management of stroke patients by the stroke team members as required by the stroke center and the stroke medical director and documentation of such continued experience; (I-R,

II-R, III-R, IV-R)

G. Review of regional outcome data on quality of patient care by the stroke team members as part of the stroke center's performance improvement and patient safety process; and (I-R, II-R, III-R, IV-R)

H. Evidence of a written agreement between a level III stroke center and a level I or II stroke center when a level III stroke center has a supervised relationship with a physician affiliated with a level I or II stroke center. A level III stroke center which provides lytic therapy to stroke patients may have an established plan for admitting and caring for stroke patients under a supervised relationship with a physician affiliated with a level I or II stroke center. This supervised relationship shall consist of a formally established and pre-planned relationship between the centers in which a physician from a level I or level II center supervises a physician in a level III center in the evaluation of a stroke patient for lytic therapy and the care of the patient post-lytic therapy in certain circumstances where that level III center does not transfer the patient to a higher level stroke center. In this setting, management decisions, including, but not limited to, administration of lytic therapy, transfer or non-transfer of patient, and post-lytic therapy shall be made jointly between the supervising and supervised physicians. Care protocols and pathways for patients that fall into this category shall be established by both parties at the outset of the establishment of the relationship. This supervised relationship shall be established by written agreement and detail the supervision of patient care. This written agreement may also include, but not be limited to, observation of patient care, review of level III stroke center's patient encounters, review of level III center's outcomes, evaluation of the level III center's process pertaining to stroke patients, and lytic therapy and guidance on methods to improve process, performance, and outcomes.

4. The stroke center shall maintain a multidisciplinary team, in addition to the stroke team, to support the care of stroke patients. (I-R, II-R, III-R, IV-R)

A. The multidisciplinary team shall include a suitable representative from hospital units as appropriate for care of each stroke patient. The hospital units represented on the multidisciplinary team may include, but not be limited to: administration, emergency medical services, intensive care unit, radiology, pharmacy, laboratory, stroke unit, stroke rehabilitation, and discharge planning. (I-R, II-R, III-R, IV-R)

B. The multidisciplinary team members or their representatives shall attend at least half of the stroke program performance improvement and patient safety program meetings which shall be documented in the meeting minutes and/or meeting attendance documents. (I-R, II-R, III-R, IV-R)

(D) A level I stroke center shall provide the services of a neuro-interventional laboratory staffed twenty-four (24) hours a day, seven (7) days a week.

1. The staff of the neuro-interventional laboratory, referred to as the neuro-interventional laboratory team, shall consist of at least the following:

A. Neuro-interventional specialist(s); and (I-R/PA)

B. Other clinical staff as deemed necessary. (I-R/PA)

2. The stroke center neuro-interventional laboratory team shall maintain core competencies annually as required by the stroke center. (I-R/PA)

3. The hospital credentialing committee shall document that the neuro-interventional specialist(s) have completed appropriate training and conducted sufficient neuro-interventional procedures. (I-R/PA)

4. The stroke center neuro-interventional laboratory team shall remain up to date in their continuing education requirements which are set forth in section (4) of this rule. (I-R/PA)

5. Resuscitation equipment shall be available in the neuro-interventional lab. (I-R)

(E) It is recommended that a level I stroke center meet the volume for stroke patient cases that is required for eligibility by The Joint Commission in its Advanced Certification of Comprehensive Stroke Centers as posted on January 31, 2012, which is incorporated by reference in this rule and is available at The Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, IL 60181 or on The Joint Commission's website at www.jointcommission.org. This rule does not incorporate any subsequent amendments or additions.

(F) The stroke center shall appoint a physician to serve as the stroke medical director. A stroke medical director shall be appointed at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. A level I stroke medical director shall have appropriate qualifications, experience, and training. A board-certified or board-admissible neurologist or other neuro-specialty trained physician is recommended. If the stroke medical director is board-certified or board-admissible, then one (1) of the following additional qualifications shall be met and documented. If the stroke medical director is not board-certified, then two (2) of the following additional qualifications shall be met and documented:

A. Completion of a stroke fellowship; (I-R)

B. Participation (as an attendee or faculty) in one (1) national or international stroke course or conference each year or two (2) regional or state stroke courses or conferences each year; or (I-R)

C. Five (5) or more peer-reviewed publications on stroke. (I-R)

2. A level II stroke medical director shall have appropriate qualifications, experience, and training. A board-certified or board-admissible physician with training and expertise in cerebrovascular disease is recommended. If the stroke medical director is board-certified or board-admissible, then one (1) of the following additional qualifications shall be met. If the stroke medical director is not board-certified, then two (2) of the following additional qualifications shall be met and documented:

A. Completion of a stroke fellowship; (II-R)

B. Participation (as an attendee or faculty) in one (1) national or international stroke course or conference each year or two (2) regional or state stroke courses or conferences each year; or (II-R)

C. Five (5) or more peer-reviewed publications on stroke. (II-R)

3. A level III and IV stroke medical director shall have the appropriate qualifications, experience, and training. A board-certified or board-admissible physician is recommended. If the stroke medical director is not board-certified or board-admissible, then the following additional qualifications shall be met and documented:

A. Complete a minimum of ten (10) hours of continuing medical education (CME) in the area of cerebrovascular disease every other year; and (III-R, IV-R)

B. Attend one (1) national, regional, or state meeting every three (3) years in cerebrovascular disease. Continuing medical education hours earned at these meetings can count toward the ten (10) required continuing medical education hours. (III-R, IV-R)

4. The stroke medical director shall meet the department's continuing medical education requirements for stroke medical directors as set forth in section (4) of this rule. (I-R, II-R, III-R, IV-R)

5. The stroke center shall have a job description and organizational chart depicting the relationship between the stroke medical director and the stroke center services. (I-R, II-R, III-R, IV-R)

6. The stroke medical director is encouraged to be a member of the stroke call roster. (I-R, II-R, III-R, IV-R)

7. The stroke medical director shall be responsible for the oversight of the education and training of the medical and clinical staff in stroke care. This includes a review of the appropriateness of the education and training for the practitioner's level of responsibility. (I-R, II-R, III-R, IV-R)

8. The stroke medical director shall participate in the stroke center's research and publication projects. (I-R)

(G) The stroke center shall have a stroke program manager/coordinator who is a registered nurse or qualified individual. The stroke center shall have a stroke program manager/coordinator at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. The stroke center shall have a job description and organizational chart depicting the relationship between the stroke program manager/coordinator and the stroke center services. (I-R, II-R, III-R, IV-R)

2. The stroke program manager/coordinator shall—

A. Meet continuing education requirements as set forth in section (4) of this rule; and (I-R, II-R, III-R, IV-R)

B. Participate in the performance improvement and patient safety program. (I-R, II-R, III-R, IV-R)

(H) The stroke center shall have a specific and well-organized system to notify and rapidly activate the stroke team to evaluate patients presenting at the stroke center with symptoms suggestive of an acute stroke. (I-R, II-R, III-R, IV-R)

(I) The stroke center shall have a one- (1-) call stroke team activation protocol. This protocol shall establish the following:

1. The criteria used to triage stroke patients shall include, but not be limited to, the time of symptom onset; (I-R, II-R, III-R, IV-R)

2. The persons authorized to notify stroke team members when a suspected stroke patient is in route and/or when a suspected stroke patient has arrived at the stroke center; (I-R, II-R, III-R, IV-R)

3. The method for immediate notification and the response requirements for stroke team members when a suspected stroke patient is in route to the stroke center and/or when a suspected stroke patient has arrived at the stroke center; and (I-R/IA, II-R/IA, III-R/IA, IV-R/IA)

4. All members of the stroke call roster shall comply with the availability and response requirements per the stroke center's protocols and be in communication within fifteen (15) minutes of notification of the patient. If not on the stroke center's premises, stroke call roster members who are on call shall carry electronic communication devices at all times to permit contact by the hospital. It is recommended that one (1) member of the stroke team, per stroke center protocol, be at the patient's bedside within fifteen (15) minutes of notification of the patient. (I-R, II-R, III-R, IV-R)

(J) The stroke center shall have a fibrinolysis protocol for cases when fibrinolysis is achievable. (I-R, II-R, III-R)

(K) The stroke center shall have transfer agreements between referring and receiving facilities that address the following:

1. A one- (1-) call transfer protocol that establishes the criteria used to triage stroke patients and identifies persons authorized to notify the designated stroke center; and (I-R, II-R, III-R, IV-R)

2. A rapid transfer process in place to transport a stroke patient to a higher level of stroke care when needed. (II-R, III-R, IV-R)

(L) The stroke center shall have rehabilitation services that are directed by a physician with board certification in physical medicine and rehabilitation or by other properly trained individuals (e.g., neurologist experienced in stroke rehabilitation). (I-R, II-R)

(M) The stroke center shall have consults for physical medicine and rehabilitation, physical therapy, occupational therapy, and speech therapy requested and completed when deemed medically necessary within forty-eight (48) hours of admission. (I-R, II-R)

(N) The stroke center shall demonstrate that there is a plan for adequate post-discharge and post-transfer follow-up on stroke patients, including rehabilitation and repatriation, if indicated. (I-R, II-R, III-R, IV-R)

(O) The stroke center shall maintain a stroke patient log. The log information shall be kept for a period of five (5) years and made available to the Department of Health and Senior Services (department) during reviews for all stroke patients which contains the following:

1. Response times; (I-R, II-R, III-R, IV-R)

2. Patient diagnosis; (I-R, II-R, III-R, IV-R)

3. Treatment/actions; (I-R, II-R, III-R, IV-R)

4. Outcomes; (I-R, II-R, III-R, IV-R)

5. Number of patients; and (I-R, II-R, III-R, IV-R)

6. Benchmark indicators. (I-R, II-R, III-R, IV-R)

(P) The stroke center shall have a helicopter landing area. (I-R, II-R, III-R, IV-R)

1. Level I and II stroke centers shall have a lighted designated helicopter landing area at the stroke center to accommodate incoming medical helicopters. (I-R, II-R)

A. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R)

B. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R)

2. Level III and IV stroke centers shall have a lighted designated helicopter landing area that meets the following requirements:

A. Accommodates incoming medical helicopters; (III-R, IV-R)

B. Serves as the receiving and take-off area for medical helicopters; (III-R, IV-R)

C. Be cordoned off when in use from the general public; (III-R, IV-R)

D. Be managed to assure its continual availability and safe operation; and (III-R, IV-R)

E. Though not required, it is recommended the landing area be no more than three (3) minutes from the emergency department. (III-R, IV-R)

(Q) Stroke centers shall enter data into the Missouri stroke registry as follows:

1. All stroke centers shall submit data into the department's Missouri stroke registry on each stroke patient who is admitted to the stroke center, transferred out of the stroke center, or dies as a result of the stroke (independent of hospital admission or hospital transfer status). The data required to be submitted into the Missouri stroke registry by the stroke centers is listed and explained in the document entitled "Time Critical Diagnosis Stroke Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at www.health.mo.gov. This rule does not incorporate any subsequent amendments or additions; (I-R, II-R, III-R, IV-R)

2. The data required in paragraph (1)(Q)1. above shall be submitted electronically into the Missouri stroke registry via the department's website at www.health.mo.gov; (I-R, II-R, III-R, IV-R)

3. The data required in paragraph (1)(Q)1. above shall be submitted electronically into the Missouri stroke registry on at least a quarterly basis for that calendar year. Stroke centers have ninety (90) days after the quarter ends to submit the data electronically into the Missouri stroke registry; (I-R, II-R, III-R, IV-R)

4. The data submitted by the stroke centers shall be complete and current; and (I-R, II-R, III-R, IV-R)

5. The data shall be managed in compliance with the confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R, IV-R)

(R) A stroke center shall maintain a diversion protocol for the stroke center that is designed to allow best resource management within a given area. The stroke center shall create criteria for diversion in this diversion protocol and shall detail a performance improvement and patient safety process in the diversion protocol to review and validate the criteria for diversion created by the stroke center. The stroke center shall also collect, document, and maintain diversion information that includes at least the date, length of time, and reason for diversion. This diversion information shall be readily retrievable by the stroke center during a review by the department and shall be kept by the stroke center for a period of five (5) years. (I-R, II-R, III-R, IV-R)

(2) Medical Staffing Standards for Stroke Center Designation.

(A) The stroke center's medical staff credentialing committee shall provide a delineation of privileges for neurologists, neurosurgeons, and neuro-interventionalists, as applicable to the stroke center. (I-R, II-R)

(B) The stroke center shall credential and shall have the following types of physicians available as listed below:

1. A neurologist shall be available for consultation within fifteen (15) minutes of patient notification; (I-R)

2. A physician with experience and expertise in diagnosing and treating patients with cerebrovascular disease shall be available for consultation within fifteen (15) minutes of patient notification; (II-R)

3. A neurosurgeon as follows:

A. Neurosurgeon and back-up coverage on the call roster; (I-R/PA)

B. Neurosurgeon and back-up coverage on the call roster or available within two (2) hours by transfer agreement if not on staff; and (II-R/PA)

C. The neurosurgery staffing requirement may be fulfilled by a surgeon who has been approved by the chief of neurosurgery for care of stroke patients and shall be capable of initiating measures to stabilize the patient and perform diagnostic procedures; (I-R, II-R)

4. A neuro-interventional specialist; (I-R/PA)

5. An emergency department physician; (I-R/IH, II-R/IH, III-R/IH; IV-R/IA)

6. An internal medicine physician; (I-R/PA, II-R/PA, III-R/PA)

7. A diagnostic radiologist; and (I-R/IA, II-R/IA, III-R/IA)

8. An anesthesiologist. (I-R/PA, II-R/PA)

A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents, certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in stroke patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents or CRNAs are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is in route under the direction of the neurosurgeon, including induction of anesthesia. An anesthesiologist assistant shall practice only under the direct supervision of an anesthesiologist who is physically present or immediately available as this term is defined in section 334.400, RSMo. (I-R, II-R)

(3) Standards for Hospital Resources and Capabilities for Stroke Center Designation.

(A) The stroke center shall meet emergency department standards listed below. (I-R, II-R, III-R, IV-R)

1. The emergency department staffing shall meet the following requirements:

A. The emergency department in the stroke center shall provide immediate and appropriate care for the stroke patient; (I-R, II-R, III-R, IV-R)

B. A level I stroke center shall have a medical director of the emergency department who shall be board-certified or board-admissible in emergency medicine by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada; (I-R)

C. A level II stroke center shall have a medical director of the emergency department who shall be a board-certified or board-admissible physician; (II-R)

D. A level III and IV stroke center shall have a medical director of the emergency department who is recommended to be a board-certified or board-admissible physician; (III-R, IV-R)

E. There shall be an emergency department physician credentialed for stroke care by the stroke center covering the emergency department twenty-four (24) hours a day, seven (7) days a week; (I-R/IH, II-R/IH, III-R/IH, IV-R/IA)

F. The emergency department physician who provides coverage shall be current in continuing medical education in the area of cerebrovascular disease; (I-R, II-R, III-R, IV-R)

G. There shall be a written policy defining the relationship of the emergency department physicians to other physician members of the stroke team; (I-R, II-R, III-R, IV-R)

H. Registered nurses in the emergency department shall be current in continuing education requirements as set forth in section (4) of this rule; (I-R, II-R, III-R, IV-R)

I. All registered nurses assigned to the emergency department shall be determined to be credentialed in the care of the stroke patient by the stroke center within one (1) year of assignment and remain current in continuing education requirements as set forth in section (4) of this rule; and (I-R, II-R, III-R, IV-R)

J. The emergency department in stroke centers shall have written care protocols for identification, triage, and treatment of acute stroke patients that are available to emergency department personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R, IV-R)

2. Nursing documentation for the stroke patient shall be on a stroke flow sheet approved by the stroke medical director and the stroke program coordinator/manager. (I-R, II-R, III-R, IV-R)

3. The emergency department shall have at least the following equipment for resuscitation and life support available to the unit:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes; (I-R, II-R, III-R, IV-R)

(II) Endotracheal tubes; (I-R, II-R, III-R, IV-R)

(III) Bag-mask resuscitator; (I-R, II-R, III-R, IV-R)

(IV) Sources of oxygen; and (I-R, II-R, III-R, IV-R)

(V) Mechanical ventilator; (I-R, II-R, III-R)

B. Suction devices; (I-R, II-R, III-R, IV-R)

C. Electrocardiograph (ECG), cardiac monitor, and defibrillator; (I-R, II-R, III-R, IV-R)

D. Central line insertion equipment; (I-R, II-R, III-R)

E. All standard intravenous fluids and administration devices including intravenous catheters and intraosseous devices; (I-R, II-R, III-R, IV-R)

F. Drugs and supplies necessary for emergency care; (I-R, II-R, III-R, IV-R)

G. Two- (2-) way communication link with emergency medical service (EMS) vehicles; (I-R, II-R, III-R, IV-R)

H. End-tidal carbon dioxide monitor; and (I-R, II-R, III-R, IV-R)

I. Temperature control devices for patient and resuscitation fluids. (I-R, II-R, III-R IV-R)

4. The stroke center emergency department shall maintain equipment following the hospital's preventive maintenance schedule and document when this equipment is checked. (I-R, II-R, III-R, IV-R)

(B) The stroke center shall have a designated intensive care unit (ICU). (I-R, II-R)

1. The intensive care unit shall ensure staffing to provide appropriate care of the stroke patient. (I-R, II-R)

A. The stroke center intensive care unit shall have a designated intensive care unit medical director who has twenty-four (24) hours a day, seven (7) days a week access to a physician knowledgeable in stroke care and who meets the stroke call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R)

B. The stroke center intensive care unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the stroke call roster. (I-R/IA, II-R/IA)

C. The stroke center intensive care unit shall have a one to one (1:1) or one to two (1:2) registered nurse/patient ratio used for critically ill patients requiring intensive care unit level care. (I-R, II-R)

D. The stroke center intensive care unit shall have registered nurses in the intensive care unit who are current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R)

E. The stroke center intensive care unit shall have registered nurses in the intensive care unit who meet at least the following core credentials for care of stroke patients on a yearly basis:

(I) Care of patients after thrombolytic therapy; (I-R, II-R)

(II) Treatment of blood pressure abnormalities with parenteral vasoactive agents; (I-R, II-R)

(III) Management of intubated/ventilated patients; (I-R, II-R)

(IV) Detailed neurologic assessment and scales (e.g., National Institutes of Health Stroke Scale, Glasgow Coma Scale); (I-R, II-R)

(V) Care of patients with intracerebral hemorrhage and subarachnoid hemorrhage at all level I centers and all level II centers with neurosurgical capability; (I-R, II-R)

(VI) Function of ventriculostomy and external ventricular drainage apparatus in all level I centers and all level II centers with neurosurgical capability; and (I-R, II-R)

(VII) Treatment of increased intracranial pressure in all level I centers and all level II centers with neurosurgical capability. (I-R, II-R)

2. The stroke center intensive care unit shall have written care protocols for identification and treatment of acute stroke patients which are available to intensive care unit personnel, reviewed annually, and revised as needed. (I-R, II-R)

3. The stroke center intensive care unit shall have intensive care unit beds for stroke patients or, if space is not available in the intensive care unit, the stroke center shall make arrangements to provide the comparable level of care until space is available in the intensive care unit. (I-R, II-R)

4. The stroke center intensive care unit shall have equipment available for resuscitation and to provide life support for the stroke patient. This equipment shall include at least the following:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator; (I-R, II-R)

B. Oxygen source with concentration controls; (I-R, II-R)

C. Cardiac emergency cart, including medications; (I-R, II-R)

D. Telemetry, ECG capability, cardiac monitor, and defibrillator; (I-R, II-R)

E. Electronic pressure monitoring and pulse oximetry; (I-R, II-R)

F. End-tidal carbon dioxide monitor; (I-R, II-R)

G. Patient weighing devices; (I-R, II-R)

H. Drugs, intravenous fluids, and supplies; and (I-R, II-R)

I. Intracranial pressure monitoring devices. (I-R, II-R)

5. The intensive care unit shall check all equipment according to the hospital preventive maintenance schedule and the stroke center shall document when it is checked. (I-R, II-R)

(C) Level I and level II stroke centers shall provide a stroke unit. A level III stroke center that has an established plan for admitting and caring for stroke patients under a supervised relationship with a level I or II stroke center pursuant to subparagraph (1)(C)3.H. above shall also provide a stroke unit. (I-R, II-R, III-R)

1. The stroke center shall have a designated medical director for the stroke unit who has access to a physician knowledgeable in stroke care and who meets the stroke call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

2. The stroke center stroke unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the stroke call roster. (I-R/IA, II-R/IA, III-R/IA)

3. The stroke center stroke unit shall have registered nurses and other essential personnel on duty twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R, III-R)

4. The stroke center stroke unit shall have registered nurses who are current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

5. The stroke center stroke unit shall annually credential registered nurses that work in the stroke unit. (I-R, II-R, III-R)

6. The stroke center stroke unit shall have written care protocols for identification and treatment of acute stroke patients (e.g., lytic and post-lytic management, hemorrhagic conversion according to current best evidence) which are available to stroke unit personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R)

7. The stroke center stroke unit shall have equipment to support the care and resuscitation of the stroke patient that includes at least the following:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes, endotracheal tubes of all sizes; (I-R, II-R, III-R)

(II) Bag-mask resuscitator and sources of oxygen; and (I-R, II-R, III-R)

(III) Suction devices; (I-R, II-R, III-R)

B. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R, III-R)

C. All standard intravenous fluids and administration devices and intravenous catheters; and (I-R, II-R, III-R)

D. Drugs and supplies necessary for emergency care. (I-R, II-R, III-R)

8. The stroke center stroke unit shall maintain equipment following the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R, III-R)

(D) The stroke center shall provide radiological and diagnostic capabilities. (I-R, II-R, III-R)

1. The radiological and diagnostic capabilities shall include a documented mechanism for prioritization of stroke patients and timely interpretation to aid in patient management. (I-R, II-R, III-R)

2. The radiological and diagnostic capabilities shall include the following equipment and staffing capabilities:

A. Angiography with interventional capability available twenty-four (24) hours a day, seven (7) days a week; (I-R/PA)

B. Cerebroangiography technologist on call and available within thirty (30) minutes for emergent procedures, and on call and available within sixty (60) minutes for routine procedures, and available twenty-four (24) hours a day, seven (7) days a week; (I-R)

C. In-house computerized tomography; (I-R/IA, II-R/IA, III-R/IA)

D. Computerized tomography perfusion; (I-R/IA)

E. Computerized tomography angiography; (I-R/IA)

F. Computerized tomography technologist; (I-R/IH, II-R/IH, III-R/IA)

G. Magnetic resonance imaging; (I-R, II-R)

H. Magnetic resonance angiogram/magnetic resonance venography; (I-R, II-R)

I. Magnetic resonance imaging technologist on call and available within sixty (60) minutes, twenty-four (24) hours a day, seven (7) days a week; (I-R, II-R)

J. Extracranial ultrasound; (I-R, II-R)

K. Equipment and clinical staff to evaluate for vasospasm available within thirty (30) minutes for emergent evaluation, and available within sixty (60) minutes for routine evaluation, and available twenty-four (24) hours a day, seven (7) days a week; (I-R)

L. Transthoracic echo; (I-R, II-R)

M. Transesophageal echo; and (I-R, II-R)

N. Resuscitation equipment available to the radiology department. (I-R, II-R, III-R)

3. The radiological and diagnostic capabilities shall include adequate physician and nursing personnel available with monitoring equipment to fully support the acute stroke patient and provide documentation of care during the time the patient is physically present in the radiology department and during transportation to and from the radiology department. (I-R, II-R, III-R)

4. The radiological and diagnostic capabilities shall include the stroke center maintaining all radiology and diagnostic equipment according to the hospital preventive maintenance schedule and documenting when it is checked. (I-R, II-R, III-R)

(E) All level I stroke centers shall have operating room personnel, equipment, and procedures. Those level II stroke centers with neurosurgical capability shall also meet operating room personnel, equipment, and procedure requirements. (I-R, II-R)

1. Operating room staff shall be available twenty-four (24) hours a day, seven (7) days a week. (I-R/PA, II-R/PA)

2. Registered nurses shall annually maintain core competencies as required by the stroke center.

3. Operating rooms shall have at least the following equipment:

A. Operating microscope; (I-R, II-R)

B. Thermal control equipment for patient and resuscitation fluids; (I-R, II-R)

C. X-ray capability; (I-R, II-R)

D. Instruments necessary to perform an open craniotomy; (I-R, II-R)

E. Monitoring equipment; and (I-R, II-R)

F. Resuscitation equipment available to the operating room. (I-R, II-R)

4. The operating room shall maintain all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(F) All level I stroke centers shall meet post-anesthesia recovery room (PAR) requirements listed below. Those level II stroke centers with neurosurgical capability shall also have a post-anesthesia recovery room and meet the requirements below—

1. The stroke center post-anesthesia recovery room shall have registered nurses and other essential personnel on call and available within sixty (60) minutes twenty-four (24) hours a day, seven (7) days a week; (I-R, II-R)

2. The stroke center post-anesthesia recovery room's registered nurses shall annually maintain core competencies as required by the stroke center; (I-R, II-R)

3. The stroke center post-anesthesia recovery room shall have at least the following equipment for resuscitation and to provide life support for the stroke patient:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen, and mechanical ventilator; (I-R, II-R)

B. Suction devices; (I-R, II-R)

C. Telemetry, ECG capability, cardiac monitor, and defibrillator; (I-R, II-R)

D. All standard intravenous fluids and administration devices, including intravenous catheters; and (I-R, II-R)

E. Drugs and supplies necessary for emergency care; and (I-R, II-R)

4. The stroke center post-anesthesia recovery room shall maintain all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(G) The stroke center shall have clinical laboratory services available twenty-four (24) hours a day, seven (7) days a week that meet the following requirements:

1. Written protocol to provide timely availability of results; (I-R, II-R, III-R, IV-R)

2. Standard analyses of blood, urine, and other body fluids; (I-R, II-R, III-R, IV-R)

3. Blood typing and cross-matching; (I-R, II-R, III-R)

4. Coagulation studies; (I-R, II-R, III-R, IV-R)

5. Comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (I-R, II-R, III-R)

6. Blood bank or access to a community central blood bank and adequate hospital blood storage facilities; (IV-R)

7. Blood gases and pH determinations; (I-R, II-R, III-R, IV-R)

8. Blood chemistries; and (I-R, II-R, III-R, IV-R)

9. Written protocol for prioritization of the stroke patient with other time critical patients. (I-R, II-R, III-R, IV-R)

(H) The stroke center shall have support services to assist the patient's family from the time of entry into the facility to the time of discharge and records to document that these services were provided. (I-R, II-R, III-R, IV-R)

(I) The stroke center shall have a stroke rehabilitation program or a plan to refer those stroke patients that require rehabilitation to another facility or community agency that can provide necessary services. (I-R, II-R, III-R)

(4) Continuing Medical Education (CME) and Continuing Education Standards for Stroke Center Designation.

(A) The stroke center shall ensure that staff providing services to stroke patients receives required continuing medical education and continuing education and document this continuing medical education and continuing education for each staff member. The department shall allow up to one (1) year from the date of the hospital's initial stroke center designation for stroke center staff members to complete all of the required continuing medical education and continuing education if the stroke center staff complete and document that at least half of the required continuing medical education and/or continuing education hours have been completed for

each stroke center staff member at the time of on-site initial application review. The stroke center shall submit documentation to the department within one (1) year of the initial designation date that all continuing medical education and continuing education requirements for stroke center staff members have been met in order to maintain the stroke center's designation. (I-R, II-R, III-R, IV-R)

(B) The stroke call roster members shall complete the following continuing education requirements:

1. Level I core team members of the stroke call roster shall complete a minimum of ten (10) hours of continuing education in cerebrovascular disease every year, and it is recommended that a portion of those hours shall be on stroke care. All other members of the stroke call roster in level I stroke centers shall complete a minimum average of ten (10) hours of continuing education in cerebrovascular disease every year. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director; (I-R)

2. Level II core team members of the stroke call roster shall complete a minimum of eight (8) hours of continuing education in cerebrovascular disease every year, and it is recommended that a portion of those hours be in stroke care. All other members of the stroke call roster in level II stroke centers shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every year. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director; and (II-R)

3. Level III and IV stroke call roster members shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every two (2) years. This continuing education shall be reviewed for appropriateness to the practitioner's level of responsibility by the stroke medical director. (III-R, IV-R)

(C) The stroke medical director shall complete the following continuing medical education requirements:

1. Level I stroke medical directors shall complete a minimum of twelve (12) hours of continuing medical education every year in the area of cerebrovascular disease; (I-R)

2. Level II stroke medical directors shall complete a minimum of eight (8) hours of continuing medical education every year in the area of cerebrovascular disease; and (II-R)

3. Level III and IV stroke medical directors shall complete a minimum of eight (8) hours of continuing medical education every two (2) years in the area of cerebrovascular disease. (III-R, IV-R)

(D) The stroke center's stroke program manager/coordinator shall complete the following continuing education requirements:

1. Level I program managers/coordinators shall:

A. Complete a minimum of ten (10) hours of continuing education every year in cerebrovascular disease. This continuing education shall be reviewed by the stroke medical director for appropriateness to the stroke program manager/coordinator's level of responsibility; and (I-R)

B. Attend one (1) national, regional, or state meeting every two (2) years focused on the area of cerebrovascular disease. If the national or regional meeting provides continuing education, then that continuing education may count toward the annual requirement; (I-R)

2. Level II program managers/coordinators shall—

A. Complete a minimum average of eight (8) hours of continuing education every year in cerebrovascular disease. This continuing education shall be reviewed for appropriateness by the stroke medical director to the stroke program manager/coordinator's level of responsibility; and (II-R)

B. Attend one (1) national, regional, or state meeting every three (3) years focused on the area of cerebrovascular disease. If the national, regional, or state meeting provides continuing education, then that continuing education may count toward the annual requirement; and (II-R)

3. Level III and IV center program managers/coordinators shall complete a minimum average of eight (8) hours of continuing education in cerebrovascular disease every two (2) years. This continuing education shall be reviewed by the stroke medical director for appropriateness to the stroke program manager/coordinator's level of responsibility. (III-R, IV-R)

(E) Emergency department personnel in stroke centers shall complete the following continuing education requirements:

1. Emergency department physicians in stroke centers shall complete—

A. Level I and II emergency department physicians providing stroke coverage shall complete a minimum average of four (4) hours of continuing medical education in cerebrovascular disease every year; or (I-R, II-R)

B. Level III and IV emergency department physicians providing stroke coverage shall complete a minimum average of six (6) hours of continuing medical education in cerebrovascular disease every two (2) years; and (III-R, IV-R)

2. Registered nurses assigned to the emergency departments in stroke centers shall complete—

A. Level I and II registered nurses shall complete a minimum of four (4) hours of cerebrovascular disease continuing education every year; (I-R, II-R)

B. Level III and IV registered nurses shall complete a minimum of six (6) hours of cerebrovascular disease continuing education every two (2) years; and (III-R, IV-R)

C. Registered nurses shall maintain core competencies in the care of the stroke patient annually as determined by the stroke center. Training to maintain these competencies may count toward continuing education requirements. (I-R, II-R, III-R, IV-R)

(F) Registered nurses assigned to the intensive care unit in the stroke centers who care for stroke patients shall complete the following continuing education requirements:

1. Level I intensive care unit registered nurses shall complete a minimum of ten (10) hours of cerebrovascular related continuing education every year; (I-R)

2. Level II intensive care unit registered nurses shall complete a minimum of eight (8) hours of cerebrovascular related continuing education every year; and (II-R)

3. The stroke medical director shall review the continuing education for appropriateness to the practitioner's level of responsibility. (I-R, II-R)

(G) Stroke unit registered nurses in the stroke centers shall complete the following continuing education requirements:

1. All level I stroke unit registered nurses shall complete a minimum of ten (10) hours of cerebrovascular disease continuing education every year; (I-R)

2. All level II stroke unit registered nurses shall complete a minimum of eight (8) hours of cerebrovascular disease continuing education every year; (II-R)

3. All level III stroke centers caring for stroke patients under an established plan for admitting and caring for stroke patients under a supervised relationship with a physician affiliated with a level I or II stroke center shall require registered nurses in the stroke unit complete a minimum of eight (8) hours of cerebrovascular disease continuing education every two (2) years; and (III-R)

4. The stroke medical director shall review the continuing education for appropriateness to the practitioner's level of responsibility. (I-R, II-R, III-R)

(5) Standards for Hospital Performance Improvement and Patient Safety, Outreach,

Public Education, and Training Programs for Stroke Center Designation.

(A) The stroke center shall maintain an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review, and evaluate the quality, timeliness, and appropriateness of patient care; resolve problems; and improve patient care. (I-R, II-R, III-R, IV-R)

1. The stroke center shall collect, document, trend, maintain for at least five (5) years, and make available for review by the department at least the following data elements:

A. Door-to-needle time; (I-R, II-R, III-R)

B. Number of patients presenting within the treatment window; and (I-R, II-R, III-R)

C. Number of eligible patients treated with thrombolytics. (I-R, II-R, III-R)

2. The stroke center shall at least quarterly conduct a regular morbidity and mortality review meeting which shall be documented in the meeting minutes and/or the meeting attendance documents. (I-R, II-R, III-R, IV-R)

3. The stroke center shall review the reports generated by the department from the Missouri stroke registry. (I-R, II-R, III-R, IV-R)

4. The stroke center shall conduct monthly reviews of pre-hospital stroke care including inter-facility transfers. (I-R, II-R, III-R, IV-R)

5. The stroke center shall participate in the emergency medical services regional system of stroke care in its respective emergency medical services region as defined in 19 CSR 30-40.302. (I-R, II-R, III-R, IV-R)

6. The stroke center shall document review of its cases of stroke patients who received U.S. Food and Drug Administration-approved thrombolytics and who remained at the referring hospital greater than ninety (90) minutes prior to transfer. (I-R, II-R, III-R)

7. The stroke center shall document its review of cases of stroke patients who did not receive U.S. Food and Drug Administration-approved thrombolytics and who remained greater than sixty (60) minutes at the referring hospital prior to transfer. (II-R, III-R, IV-R)

8. The stroke center shall review and monitor the core competencies of the physicians, practitioners, and nurses and document these core competencies have been met. (I-R, II-R, III-R, IV-R)

(B) The stroke center shall establish a patient and public education program to promote stroke prevention and stroke symptoms awareness. (I-R, II-R, III-R, IV-R)

(C) It is recommended that level I, II, and III stroke centers establish a professional education outreach program in catchment areas to provide training and other supports to improve care of stroke patients. (I-R, II-R, III-R)

(D) Each stroke center shall establish a training program for professionals on caring for stroke patients in the stroke center that includes at least the following:

1. A procedure for training nurses and clinical staff to be credentialed in stroke care; (I-R, II-R, III-R, IV-R)

2. A mechanism to assure that all nurses providing care to stroke patients complete a minimum of required continuing education as set forth in section (4) of this rule to become credentialed in stroke care; and (I-R, II-R, III-R, IV-R)

3. The content and format of any stroke continuing education courses developed and offered by the stroke center shall be developed with the oversight of the stroke medical director. (I-R, II-R, III-R, IV-R)

(E) The stroke center shall provide and monitor timely feedback to the emergency medical service providers and referring hospital, if involved. This feedback shall include, at least, diagnosis, treatment, and disposition of the patients. It is recommended that the feedback be provided within seventy-two (72) hours of admission to the hospital. When emergency medical services does not provide patient care data on patient arrival or in a timely fashion (recommended within three (3) hours of patient delivery), this time frame shall not apply. (I-R, II-R, III-R, IV-R)

(F) Stroke centers shall be actively involved in local and regional emergency medical services systems by providing training and clinical educational resources. (I-R, II-R, III-R, IV-R)

(6) Standards for the Programs in Stroke Research for Stroke Center Designation.

(A) Level I stroke centers shall support an ongoing stroke research program as evidenced by any of the following:

1. Production of evidence-based reviews of the stroke program's process and clinical outcomes; (I-R)

2. Publications in peer-reviewed journals; (I-R)

3. Reports of findings presented at regional, state, or national meetings; (I-R)

4. Receipt of grants for study of stroke care; (I-R)

5. Participation in multi-center studies; and (I-R)

6. Epidemiological studies and individual case studies. (I-R)

(B) The stroke center shall agree to cooperate and participate with the department in developing stroke prevention programs. (I-R, II-R, III-R, IV-R)

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.740 Definitions and Abbreviations Relating to ST-Segment Elevation Myocardial Infarction (STEMI) Centers

PURPOSE: This rule defines terminology related to STEMI centers.

(1) For the purposes of 19 CSR 30-40.750 and 19 CSR 30-40.760 the following terms shall mean:

(A) Acute—an injury or illness that happens or appears quickly and can be serious or life-threatening;

(B) Anesthesiologist assistant (AA)—a person who—

1. Has graduated from an anesthesiologist assistant program accredited by the American Medical Association's Committee on Allied Health Education and Accreditation or by its successor agency;

2. Has passed the certifying examination administered by the National Commission on Certification of Anesthesiologist Assistants;

3. Has active certification by the National Commission on Certification of Anesthesiologist Assistants;

4. Is currently licensed as an anesthesiologist assistant in the state of Missouri; and

5. Provides health care services delegated by a licensed anesthesiologist;

(C) Board-admissible/board-eligible—a physician who has applied to a specialty board of the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada and has received a ruling that he or she has fulfilled the requirements to take the examinations. Board certification is generally obtained within five (5) years of the first appointment;

(D) Board-certified—a physician who has fulfilled all requirements, has satisfactorily completed the written and oral examinations, and has been awarded a board diploma in a specialty field by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic

Specialists, or the Royal College of Physicians and Surgeons of Canada;

(E) Cardiac catheterization laboratory—the setting within the hospital where percutaneous coronary interventions are done. Specialized staff, equipment, and protocol must be in place;

(F) Cardiac catheterization team—physicians and clinical staff who perform percutaneous coronary interventions and who are part of the clinical STEMI team;

(G) Cardiogenic shock—a life threatening condition in which the heart muscle does not pump enough blood to meet the body's needs;

(H) Cardiologist—a licensed physician with appropriate specialty training;

(I) Cardiology Service—an organizational component of the hospital specializing in the care of patients who have had STEMIs or some other cardiovascular condition or disorder;

(J) Catchment area—the surrounding area served by the institution (the STEMI center);

(K) Certified registered nurse anesthetist (CRNA)—a registered nurse who—

1. Has graduated from a school of nurse anesthesia accredited by the Council on Accreditation of Educational Programs of Nurse Anesthesia or its predecessor;

2. Has been certified as a nurse anesthetist by the Council on Certification of Nurse Anesthetists; and

3. Has been licensed in Missouri pursuant to Chapter 335, RSMo;

(L) Clinical staff—an individual that has specific training and experience in the treatment and management of STEMI patients. Examples include physicians, registered nurses, advanced practice nurses, physician assistants, pharmacists, and technologists;

(M) Clinical team—a team of health care professionals involved in the care of the STEMI patient and may include, but not be limited to, cardiologists, interventional cardiologists, cardiovascular surgeons, anesthesiologists, emergency medicine, and other STEMI center clinical staff. The clinical team is part of the hospital's STEMI team;

(N) Contiguous leads—the electrical cables that attach the electrodes on the patient to the electrocardiograph recorder and which are next to one another. They view the same general area of the heart;

(O) Continuing education—education approved or recognized by a national and/or state professional organization and/or STEMI medical director;

(P) Continuing medical education (CME)—the highest level of continuing education for physicians that is approved by a national and/or state professional organization and/or STEMI medical director;

(Q) Core team—a subunit of the hospital STEMI team which consists of a physician experienced in diagnosing and treating STEMI (usually the STEMI medical director) and at least one (1) other health care professional or qualified individual competent in STEMI care as determined by the hospital (usually the STEMI program manager/coordinator);

(R) Credentialed or credentialing—a hospital-specific system of documenting and recognizing the qualifications of medical staff and nurses and authorizing the performance of certain procedures and establishing clinical privileges in the hospital setting;

(S) Department—the Missouri Department of Health and Senior Services;

(T) Door-to-balloon-time—the time from arrival at the hospital door to percutaneous coronary intervention balloon inflation for the purpose of restoring blood flow in an obstructed coronary artery in the cardiac catheterization lab. This term is commonly abbreviated as D2B;

(U) Door-to-device-time—the time from patient arrival at the hospital to the time the device is in the affected cardiac blood vessel;

(V) Door-to-needle-time—the time from arrival at the hospital door to initiation of lytic therapy to restore blood flow in an obstructed blood vessel;

(W) Electrocardiogram (ECG/EKG)—a recorded tracing of the electrical activity of the heart. The heart rate, heartbeat regularity, size and chamber position, presence of any prior heart attack, current injury, and the effects of drugs or devices (i.e., pacemaker can be determined). An abnormal ECG pattern is seen during a heart attack because damaged areas of the heart muscle do not conduct electricity properly;

(X) Emergency medical service regions—the six (6) regions in the state of Missouri which are defined in 19 CSR 30-40.302;

(Y) First medical contact—a patient's initial contact with a health-care provider either pre-hospital, which could be contact with emergency medical service personnel or another medical provider, or in the hospital;

(Z) First medical contact to balloon or device time—the time from a patient's first medical contact with a health-care provider to the time when the balloon is inflated or the device is in the affected cardiac blood vessel;

(AA) First medical contact to hospital door time—the time from a patient's first medical contact with a health-care provider to the time when the patient arrives at the hospital door;

(BB) Hospital—an establishment as defined by section 197.020.2, RSMo, or a hospital operated by the state;

(CC) Immediately available (IA)—being present at bedside at the time of the patient's arrival at the hospital when prior notification is possible and no more than twenty (20) minutes from the hospital under normal driving and weather conditions;

(DD) In-house (IH)—being on the hospital premises twenty-four (24) hours a day;

(EE) Intermediate care unit—the functional division or facility of the hospital that provides care for STEMI patients admitted to the STEMI center;

(FF) Interventional cardiologist—a licensed cardiologist with the appropriate specialty training;

(GG) Lytic therapy (fibrinolysis/thrombolysis)—drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(HH) Mentoring relationship—a relationship in which a high volume percutaneous coronary interventions operator, often described as performing one hundred fifty (150) or more procedures per year, serves as a mentor for an operator who performs less than eleven (11) primary percutaneous coronary interventions per year;

(II) Missouri STEMI registry—a statewide data collection system comprised of key data elements as identified by the Department of Health and Senior Services used to compile and trend statistics of STEMI patients both pre-hospital and hospital, using a coordinated electronic reporting method provided by the Missouri Department of Health and Senior Services;

(JJ) Multidisciplinary team—a team of appropriate representatives of hospital units involved in the care of the STEMI patient. This team supports the care of the STEMI patient with the STEMI team;

(KK) Patient—an individual who is sick, injured, wounded, diseased, or otherwise incapacitated or helpless, or dead, excluding deceased individuals being transported from or between private or public institutions, homes, or cemeteries, and individuals declared dead prior to the time an ambulance is called for assistance;

(LL) Peer review system—is the process the STEMI center establishes for physicians to review STEMI cases on patients that are admitted to the STEMI center, transferred out of the STEMI center, or die as a result of

the STEMI (independent of hospital admission or hospital transfer status);

(MM) Percutaneous coronary intervention (PCI)—is a procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart. A primary percutaneous coronary intervention is one that is generally done on an emergency basis for a ST-elevation myocardial infarction (STEMI). Treatment occurs while the blood clot is still forming—usually within twenty-four (24) hours of onset, but ideally within two (2) hours of symptoms onset. An elective percutaneous coronary intervention is one that is done on a non-urgent basis to reduce signs and symptoms of angina;

(NN) Percutaneous coronary intervention window—the time frame in which percutaneous coronary intervention is most advantageous and recommended;

(OO) Phase I cardiac rehabilitation—an inpatient program that provides an individualized exercise and education plan for patients with cardiac illnesses;

(PP) Physician—a person licensed as a physician pursuant to Chapter 334, RSMo;

(QQ) Promptly available (PA)—arrival at the hospital at the patient's bedside within thirty (30) minutes after notification of a patient's arrival at the hospital;

(RR) Protocol—a predetermined, written medical care guideline, which may include standing orders;

(SS) Qualified individual—a physician, registered nurse, advanced practice registered nurse, and/or physician assistant that demonstrates administrative ability and shows evidence of educational preparation and clinical experience in the care of STEMI patients and is licensed by the state of Missouri;

(TT) Regional outcome data—data used to assess the regional process for pre-hospital, hospital, and regional patient outcomes;

(UU) Repatriation—the process used to return a STEMI patient to his or her home community from a level I or level II STEMI designated hospital after his or her acute treatment for STEMI has been completed. This allows the patient to be closer to home for continued hospitalization or rehabilitation and follow-up care as indicated by the patient's condition;

(VV) Reperfusion—the process of restoring normal blood flow to an organ or tissue that has had its blood supply cut off, such as after an ischemic stroke or myocardial infarction;

(WW) Requirement (R)—a symbol to indicate that a standard is a requirement for STEMI center designation at a particular level;

(XX) Review—is the inspection of a hospital to determine compliance with the rules of this chapter;

(YY) ST-elevation myocardial infarction (STEMI)—a myocardial infarction for which the electrocardiogram shows ST-segment elevation, usually in association with an acutely blocked coronary artery. A STEMI is one type of heart attack that is a potentially lethal condition for which specific therapies, administered rapidly, reduce mortality and disability. The more time that passes before blood flow is restored, the more damage that is done to the heart muscle;

(ZZ) STEMI call roster—a schedule that provides twenty-four (24) hours a day, seven (7) days a week cardiology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of the STEMI patients;

(AAA) STEMI care—education, prevention, emergency transport, triage, acute care, and rehabilitative services for STEMI that requires immediate medical or surgical intervention or treatment;

(BBB) STEMI center—a hospital that is currently designated as such by the department to care for patients with ST-segment elevation myocardial infarctions.

1. A level I STEMI center is a receiving center staffed and equipped to provide total care for every aspect of STEMI care, including care for those patients with complications. It functions as a resource center for the hospitals within that region and conducts research.

2. A level II STEMI center is a receiving center staffed and equipped to provide care for a large number of STEMI patients within the region.

3. A level III STEMI center is primarily a referral center that provides prompt assessment, indicated resuscitation, and appropriate emergency intervention for STEMI patients to stabilize and arrange timely transfer to a Level I or II STEMI center, as needed.

4. A level IV STEMI center is a referral center in an area considered rural or where there are insufficient hospital resources to serve the patient population requiring STEMI care. The level IV STEMI center provides prompt assessment, indicated resuscitation, appropriate emergency intervention, and arranges and expedites transfer to a higher level STEMI center as needed;

(CCC) STEMI identification—a diagnosis is made on a basis of symptoms, clinical examination, and electrocardiogram changes, specifically ST-segment elevation;

(DDD) STEMI medical director—a physician designated by the hospital who is responsible for the STEMI service and performance improvement and patient safety programs related to STEMI care;

(EEE) STEMI program—an organizational component of the hospital specializing in the care of STEMI patients;

(FFF) STEMI program manager—a qualified individual designated by the hospital with responsibility for monitoring and evaluating the care of STEMI patients and the coordination of performance improvement and patient safety programs for the STEMI center in conjunction with the physician in charge of STEMI care;

(GGG) STEMI team—a component of the hospital STEMI program which consists of the core team and the clinical team;

(HHH) Symptom onset-to-treatment time—the time from symptom onset to initiation of therapy to restore blood flow in an obstructed blood vessel;

(III) Thrombolytics—drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction; and

(JJJ) Transfer agreement—a document which sets forth the rights and responsibilities of two (2) hospitals regarding the inter-hospital transfer of patients.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.750 ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation Application and Review

PURPOSE: This rule establishes the requirements for participation in Missouri's STEMI center program.

(1) Participation in Missouri's STEMI center program is voluntary and no hospital shall be required to participate. No hospital shall hold itself out to the public as a state-designated STEMI center unless it is designated as such by the Department of Health and Senior Services (department). Hospitals desiring STEMI center designation shall apply to the department. Only those hospitals found by review to be in compliance with the requirements of the rules of this chapter shall be designated by the department as STEMI centers.

(A) An application for STEMI center designation shall be made upon forms prepared or prescribed by the department and shall contain information the department deems necessary to make a fair determination of eligibility for review and designation in accordance with the rules of this chapter. The STEMI center review and designation application form, included herein, is available at the Health Standards and Licensure (HSL) office, or online at the department's website at www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570. The application for STEMI center designation shall be submitted to the department no less than sixty (60) days and no more than one hundred twenty (120) days prior to the desired date of the initial designation or expiration of the current designation.

(B) Both sections A and B of the STEMI center review and designation application form, included herein, shall be complete before the department will arrange a date for the review. The department shall notify the hospital/STEMI center of any apparent omissions or errors in the completion of the STEMI center review and designation application form. When the STEMI center review and designation application form is complete, the department shall contact the hospital/STEMI center to arrange a date for the review.

(C) The hospital/STEMI center shall cooperate with the department in arranging for a mutually suitable date for any announced reviews.

(2) The different types of reviews to be conducted on hospitals/STEMI centers include:

(A) An initial review shall occur on a hospital applying to be initially designated as a STEMI center. An initial review shall include interviews with designated hospital staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter;

(B) A validation review shall occur on a designated STEMI center applying for renewal of its designation as a STEMI center. Validation reviews shall occur no less than every three (3) years. A validation review shall include interviews with designated STEMI center staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter; and

(C) A focus review shall occur on a designated STEMI center in which a validation review was conducted and substantial deficiency(ies) were cited. A review of the physical plant will not be necessary unless a deficiency(ies) was cited in the physical plant in the preceding validation review. The focus review team shall be comprised of a representative from the department and may include a qualified contractor(s) with the required expertise to evaluate corrections in areas where deficiencies were cited.

(3) STEMI center designation shall be valid for a period of three (3) years from the date the STEMI center/hospital is designated.

(A) STEMI center designation shall be site specific and non-transferable when a STEMI center changes location.

(B) Once designated as a STEMI center, a STEMI center may voluntarily surrender the designation at any time without giving cause, by contacting the department in writing. In these cases, the application and review process shall be completed again before the designation may be reinstated.

(4) For the purpose of reviewing previously designated STEMI centers and hospitals applying for STEMI center designation, the department shall use review teams consisting of qualified contractors. These review teams shall consist of one (1) STEMI coordinator or STEMI program manager who has experience in STEMI care and one (1) emergency medicine physician experienced in STEMI care. The review team shall also consist of at least (1) one and no more than two (2) cardiologist(s)/interventional cardiologist(s) who are experts in STEMI care. One (1) representative from the department will also be a participant of the review team. This representative shall coordinate the review with the hospital/STEMI center and the other review team members.

(A) Any individual interested in becoming a qualified contractor to conduct reviews shall—

1. Send the department a curriculum vitae (CV) or resume that includes his or her experience and expertise in STEMI care and whether an individual is in good standing with his or her licensing boards. A qualified contractor shall be in good standing with his or her respective licensing boards;

2. Provide the department evidence of his or her previous site survey experience (state and/or national designation survey process); and

3. Submit a list to the department that details any ownership he or she may have in a Missouri hospital(s), whether he or she has been terminated from any Missouri hospital(s), any lawsuits he or she has currently or had in the past with any Missouri hospital(s), and any Missouri hospital(s) for which his or her hospital privileges have been revoked.

(B) Qualified contractors for the department shall enter into a written agreement with the department indicating, that among other things, they agree to abide by Chapter 190, RSMo, and the rules in this chapter, during the review process.

(5) Out-of-state review team members shall conduct levels I and II hospital/STEMI center reviews. Review team members are considered out-of-state review team members if they work outside of the state of Missouri. In-state review team members may conduct levels III and IV hospital/STEMI center reviews. Review team members are considered in-state review team members if they work in the state of Missouri. In the event that out-of-state reviewers are unavailable, levels I and II STEMI center reviews may be conducted by in-state reviewers from Emergency Medical Services (EMS) regions as set forth in 19 CSR 30-40.302 other than the region being reviewed with the approval of the director of the department or his/her designee. When utilizing in-state review teams, level I and II hospital/STEMI centers shall have the right to refuse one (1) in-state review team or certain members from one (1) in-state review team.

(6) Hospitals/STEMI centers shall be responsible for paying expenses related to the costs of the qualified contractors to review their respective hospital/STEMI center during initial, validation, and focus reviews. The department shall be responsible for paying the expenses of its representative. Costs of the review to be paid by the hospital/STEMI center include:

(A) An honorarium shall be paid to each qualified contractor of the review team. Qualified contractors of the review team for level I and II STEMI center reviews shall be paid six hundred dollars ($600) for the day of travel per reviewer and eight hundred fifty dollars ($850) for the day of the review per reviewer. Qualified contractors of the review team for level III and IV STEMI center reviews shall be paid five hundred dollars ($500) for the day of travel per reviewer and five hundred dollars ($500) for the day of the review per reviewer. This honorarium shall be paid to each qualified contractor of the review team at the time the site survey begins;

(B) Airfare shall be paid for each qualified contractor of the review team, if applicable;

(C) Lodging shall be paid for each qualified contractor of the review team. The hospital/STEMI center shall secure the appropriate number of hotel rooms for the qualified contractors and pay the hotel directly; and

(D) Incidental expenses, if applicable, for each qualified contractor of the review team shall not exceed two hundred fifty dollars ($250) and may include the following:

1. Airport parking;
2. Checking bag charges;
3. Meals during the review; and
4. Mileage to and from the review if no airfare was charged by the reviewer. Mileage shall be paid at the federal mileage rate for business miles as set by the Internal Revenue Service (IRS). Federal mileage rates can be found at the website www.irs.gov.

(7) Upon completion of a review, the qualified contractors from the review team shall submit a report of their findings to the department. This report shall state whether the specific standards for STEMI center designation have or have not been met and if not met, in what way they were not met. This report shall detail the hospital/STEMI center's strengths, weaknesses, deficiencies, and recommendations for areas of improvement. This report shall also include findings from patient chart audits and a narrative summary of the following areas: prehospital, hospital, STEMI service, emergency department, operating room, angiography suites, recovery room, clinical lab, intensive care unit, rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review, and interviews. The department shall have the final authority to determine compliance with the rules of this chapter.

(8) The department shall return a copy of the report to the chief executive officer, the STEMI medical director, and the STEMI program manager/coordinator of the hospital/STEMI center reviewed. Included within the report shall be notification indicating whether the hospital/STEMI center has met the criteria for STEMI center designation or has failed to meet the criteria for STEMI center designation as requested. Also, if a focus review of the STEMI center is required, the time frame for this focus review will be shared with the chief executive officer, the STEMI medical director, and the STEMI program manager/coordinator of the STEMI center reviewed.

(9) When the hospital/STEMI center is found to have deficiencies, the hospital/STEMI center shall submit a plan of correction to the department. The plan of correction shall include identified deficiencies, actions to be taken to correct deficiencies, time frame in which the deficiencies are expected to be resolved, and the person responsible for the actions to resolve the deficiencies. A plan of correction form shall be completed by the hospital and returned to the department within thirty (30) days after notification of review findings and designation. If a focus review is required, the STEMI center shall be allowed a minimum period of six (6) months to correct deficiencies.

(10) A STEMI center shall make the department aware in writing within thirty (30) days if there are any changes in the STEMI center's name, address, contact information, chief executive officer, STEMI medical director, or STEMI program manager/coordinator.

(11) Any person aggrieved by an action of the department affecting the STEMI center designation pursuant to Chapter 190, RSMo, including the revocation, the suspension, or the granting of, refusal to grant, or failure to renew a designation, may seek a determination by the Administrative Hearing Commission under Chapter 621, RSMo. It shall not be a condition to such determination that the person aggrieved seek reconsideration, a rehearing, or exhaust any other procedure within the department.

(12) The department may deny, place on probation, suspend, or revoke such designation in any case in which it has reasonable cause to believe that there has been a substantial failure to comply with the provisions of Chapter 190, RSMo, or any rules or regulations promulgated pursuant to this chapter. If the department has reasonable cause to believe that a hospital is not in compliance with such provisions or regulations, it may conduct additional announced or unannounced site reviews of the hospital to verify compliance. If a STEMI center fails two (2) consecutive on-site reviews because of substantial noncompliance with standards prescribed by sections 190.001 to 190.245, RSMo, or rules adopted by the department pursuant to sections 190.001 to 190.245, RSMo, its center designation shall be revoked.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH SERVICES AND LICENSURE
APPLICATION FOR STEMI CENTER REVIEW AND DESIGNATION

SECTION A

In accordance with the requirements of the Chapter 190 RSMo and the applicable regulations, this application is hereby submitted for review and designation as a STEMI center. Please complete all information applicable to the requested designation level.	Designation Level Requested ☐ I ☐ II ☐ III ☐ IV

HOSPITAL INFORMATION

Name Of Hospital (Name To Appear On Designation Certificate)	Telephone Number	
Address (Street And Number)	City	Zip

PROFESSIONAL INFORMATION

Chief Executive Officer	Chairman/President of Board of Trustees
STEMI Medical Director	STEMI Program Manager
Medical Director of Emergency Medicine	Medical Director of Intensive Care/Cardiac Care Unit

RESOURCE INFORMATION

STEMI Caseload	STEMI Team Activations	Cardiac Cath Lab Team Activations for STEMI	CT Capability ☐ FULL ☐ PARTIAL ☐ NONE
MRI Capability ☐ FULL ☐ PARTIAL ☐ NONE	Cardiothoracic Surgery Capability or Plan	ICU/CCU Beds	Cath Lab Suites
Cardiac Rehab ☐ Phase I ☐ Plan for Rehab	Cardiologists	Interventional Cardiologists	Cardiothoracic Surgeons
ED Physicians	Anesthesiologists/CRNAs & AAs	Avg Elective PCI/Primary PCIs over the last 3 years (not required for initial review)	Average STEMI cases lytics eligible/STEMI cases that receive lytics in the past 3 years (not required for initial review)

CERTIFICATION

We, the undersigned, hereby certify that the information provided in this application for STEMI center review and designation is true and accurate; and give assurance of the intent and ability of the hospital to comply with regulations promulgated under Chapter 190 RSMo.

We further certify that the hospital will comply with all recommendations for improvement contained in the STEMI center site review reports prepared by the Missouri Department of Health and Senior Services.

Date of application_____

Signed_____
Chairman/President of Board of Trustees, Owner, or one Partner of Partnership

Signed_____
Hospital Chief Executive Officer

Signed_____
STEMI Medical Director

Signed_____
Director of Emergency Medicine

MO 580 EMS

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION OF HEALTH STANDARDS AND LICENSURE
APPLICATION FOR STEMI CENTER REVIEW AND DESIGNATION

SECTION B

Please attach the following documentation to the application form.

Name of Hospital:

- ☐ Hospital organizational chart depicting the relationship of the STEMI services to other services and defining the organizational structure of the STEMI service.
- ☐ Job descriptions and CV for the STEMI medical director and STEMI coordinator/program manager.
- ☐ A narrative description of the administrative commitment for the STEMI center, including how STEMI center designation relates to the overall mission of the hospital.
- ☐ A current board resolution supporting the STEMI center.
- ☐ A narrative description of the catchment area for the STEMI center.
- ☐ A narrative description of the prehospital system including the hospital's participation in medical control, quality assurance, and education of the emergency medicine personnel.
- ☐ Hospital diversion policy.
- ☐ List of the STEMI medical director and STEMI program coordinator or program manager (core STEMI team) indicating the cardiac related continuing education for each over the past three (3) years. (Do not send continuing education information about the clinical STEMI team. This should be available at the time of the review.)
- ☐ Multidisciplinary team policy.
- ☐ List of all cardiologists, cardiothoracic surgeons, interventional cardiologists and emergency department physicians indicating cardiac-related CME for each over the past three (3) years.
- ☐ List of mentors, if applicable, their relationship to the hospital and the mentor plan.
- ☐ Narrative description of the system for notifying/activating STEMI team
- ☐ Cardiac catheterization lab team activation protocol.
- ☐ One-call cardiac catheterization lab activation by EMS protocol and/or by ED protocol.
- ☐ Copies of all transfer agreements pertaining to STEMI.
- ☐ Policy for cardiac rehabilitation.
- ☐ Protocols on post-discharge and post-transfer follow-up for STEMI patients.
- ☐ A narrative description of the STEMI quality improvement (QI) processes utilized by the hospital (Do not send copies of QI minutes or documents. These should be available at the time of review.)
- ☐ Examples of STEMI-related educational, outreach, and research projects undertaken by the hospital.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.760 Standards for ST-Segment Elevation Myocardial Infarction (STEMI) Center Designation

PURPOSE: This rule establishes standards for level I, II, III, and IV STEMI center designation.

AGENCY NOTE:
I-R, II-R, III-R, or IV-R after a standard indicates a requirement for level I, II, III, or IV STEMI centers respectively.
I-IH, II-IH, III-IH, or IV-IH after a standard indicates an in-house requirement for level I, II, III, or IV STEMI centers respectively.
I-IA, II-IA, III-IA, or IV-IA indicates an immediately available requirement for level I, II, III, or IV STEMI centers respectively.
I-PA, II-PA, III-PA, or IV-PA indicates a promptly available requirement for level I, II, III, or IV STEMI centers respectively.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) General Standards for STEMI Center Designation.

(A) The STEMI center board of directors, administration, medical staff, and nursing staff shall demonstrate a commitment to quality STEMI care. Methods of demonstrating the commitment shall include, but not be limited to, a board resolution that the hospital governing body agrees to establish policy and procedures for the maintenance of services essential for a STEMI center; assure that all STEMI patients will receive medical care at the level of the hospital's designation; commit the institution's financial, human, and physical resources as needed for the STEMI program; and establish a priority admission for the STEMI patient to the full services of the institution. (I-R, II-R, III-R, IV-R)

(B) STEMI centers shall agree to accept all STEMI patients appropriate for the level of care provided at the hospital, regardless of race, sex, creed, or ability to pay. (I-R, II-R, III-R, IV-R)

(C) The STEMI center shall demonstrate evidence of a STEMI program. The STEMI program shall be available twenty-four (24) hours a day, seven (7) days a week to treat and evaluate STEMI patients. (I-R, II-R, III-R, IV-R)

1. The STEMI center shall maintain a STEMI team that at a minimum consists of—

A. A core team which provides administrative oversight and includes the following:

(I) A physician experienced in diagnosing and treating cardiovascular disease and STEMI (usually the STEMI medical director); and (I-R, II-R, III-R, IV-R)

(II) At least one (1) other health care professional or qualified individual credentialed in STEMI care (usually the STEMI program manager/coordinator); (I-R, II-R, III-R, IV-R)

B. A STEMI call roster that provides twenty-four (24) hours a day, seven (7) days a week cardiology service coverage. The call roster identifies the physicians or qualified individuals on the schedule that are available to manage and coordinate emergent, urgent, and routine assessment, diagnosis, and treatment of the STEMI patients. A level I and level II STEMI call roster shall include, but not be limited to, the emergency department physician, interventional cardiologist, and others as appropriate. The level III STEMI center call roster shall include, but not be limited to, the emergency department physician and others as appropriate. A level IV STEMI center call roster shall include, but not be limited to, the emergency department physician and other qualified individuals as appropriate. (I-R, II-R, III-R, IV-R)

(I) Level I and II STEMI centers shall have this coverage promptly available from notification of STEMI patients. (I-R, II-R)

(II) Level III and IV STEMI centers shall have a regional networking agreement with a level I or level II STEMI center for telephone consult or telemedicine consultation promptly available from notification of STEMI patients; and (I-R, II-R, III-R, IV-R)

C. A clinical team appropriate to the center level designation that may include, but not be limited to, cardiologists, interventional cardiologists, clinical perfusionists, members of the STEMI call roster, members of the cardiac catheterization team, cardiothoracic surgeons, anesthesiologists, emergency department physicians, intensivists, and other STEMI center clinical staff as applicable. (I-R, II-R, III-R, IV-R)

2. The STEMI center shall have a peer review system to review STEMI cases respective of the STEMI center's designation. (I-R, II-R, III-R, IV-R)

3. The STEMI team shall have appropriate experience to maintain skill and proficiency to care for STEMI patients. The STEMI center shall maintain evidence that it meets the following requirements by documenting the following:

A. A list of all STEMI team members; (I-R, II-R, III-R, IV-R)

B. Position qualifications and completion of continuing education requirements by STEMI team members as set forth in sections (1), (2), and (4) of this rule; (I-R, II-R, III-R, IV-R)

C. Management of sufficient numbers of STEMI patients by the STEMI team members in order to maintain their STEMI skills; (I-R, II-R, III-R, IV-R)

D. Participation by the core team and members of the STEMI call roster in at least half of the regular, ongoing STEMI program peer review system meetings as shown in meeting attendance documents. The STEMI medical director shall disseminate the information and findings from the peer review system meetings to the STEMI call roster members and the core team and document such dissemination; (I-R, II-R, III-R, IV-R)

E. Participation by STEMI team members in at least half of the regular ongoing STEMI program performance improvement and patient safety meetings and documentation of such attendance in the meeting minutes and/or meeting attendance documents. The STEMI medical director shall disseminate the information and findings from the performance improvement and patient safety meetings to the STEMI team members and document such dissemination. If a STEMI team member is unable to attend a STEMI program performance improvement and patient safety meeting, then the STEMI team member shall send an appropriate representative in his/her place; (I-R, II-R, III-R, IV-R)

F. Maintenance of skill levels in the management of STEMI patients by the STEMI team members as required by the STEMI center and the STEMI medical director and documentation of such continued experience; and (I-R, II-R, III-R, IV-R)

G. Review of regional outcome data on the quality of patient care by STEMI team members as part of the STEMI center's performance improvement and patient safety process. (I-R, II-R, III-R, IV-R)

4. The STEMI center shall maintain a multidisciplinary team, in addition to the STEMI team, to support the care of STEMI patients. (I-R, II-R, III-R, IV-R)

A. The multidisciplinary team shall include a suitable representative from hospital units as appropriate for care of each STEMI patient. The units represented on the multidisciplinary team may include, but not be limited to: administration, emergency medical services, intensive care unit, cardiac catheterization lab, pharmacy, laboratory, intermediate care unit, cardiac rehabilitation, and discharge planning. (I-R, II-R, III-R, IV-R)

B. The multidisciplinary team members or their representatives shall attend at least half of the STEMI program performance improvement and patient safety meetings which shall be documented in meeting minutes and/or meeting attendance documents. (I-R, II-R, III-R, IV-R)

(D) The STEMI center shall provide the services of a cardiac catheterization laboratory staffed twenty-four (24) hours a day, seven (7) days a week. The staff of the cardiac catheterization laboratory, referred to as the cardiac catheterization laboratory team, shall consist of at least the following:

1. An interventional cardiologist. The STEMI center credentialing committee shall document that the interventional cardiologist has completed appropriate training and conducted sufficient coronary interventional procedures. In addition, the interventional cardiologist shall annually conduct a sufficient number of percutaneous coronary interventions (PCIs). It is recommended that interventional cardiologist(s) perform seventy-five (75) or more elective percutaneous coronary interventions per interventional cardiologist per year and eleven (11) or more primary percutaneous coronary interventions per interventional cardiologist per year; and (I-R/PA, II-R/PA)

2. Other healthcare professionals as deemed necessary. (I-R/PA, II-R/PA)

(E) A level I STEMI center shall meet the following criteria:

1. It is recommended that the cardiac catheterization laboratory perform—

A. At least an average of four hundred (400) or more elective percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

B. At least an average of forty-nine (49) or more primary percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

2. On-site emergency cardiothoracic surgical services as needed twenty-four (24) hours a day, seven (7) days a week. (I-R/PA)

(F) A level II STEMI center shall meet one (1) of the two (2) options outlined below to qualify for a level II STEMI center designation—

1. Option one—

A. It is recommended that the cardiac catheterization laboratory perform—

(I) An average of two hundred (200) or more elective percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

(II) An average of thirty-six (36) or more primary percutaneous coronary interventions per year over three (3) consecutive preceding years per STEMI center; and

B. On-site emergency cardiothoracic surgical services or have a written plan that has been shown to be effective, a transfer agreement, and expedited transfer process for cardiothoracic surgery back-up in a nearby STEMI center with appropriate hemodynamic support capability for transfer. The written plan shall ensure that once a potential need for cardiothoracic intervention is identified, the STEMI patient can be evaluated by cardiothoracic surgery and in the operating room (OR) of the receiving hospital as expeditiously as possible; or (II-R)

2. Option two is a level II STEMI center that performs less than a recommended average of two hundred (200) elective percutaneous coronary interventions per year and a recommended average of thirty-six (36) or more primary percutaneous coronary interventions per year over three (3) consecutive preceding years or a recommended average of two hundred (200) elective percutaneous coronary interventions per year or more and less than a recommended average of thirty-six (36) primary percutaneous coronary interventions per year over three (3) consecutive preceding years. The following requirements for option two shall be met to qualify for a level II center designation:

A. If a STEMI center performs less than an annual recommended average of thirty-six (36) primary percutaneous coronary interventions over three (3) consecutive preceding years, it is recommended that the STEMI center perform an annual average of two hundred (200) or more elective percutaneous coronary interventions over three (3) consecutive preceding years, and it is recommended that all operators shall perform seventy-five (75) or more elective percutaneous coronary interventions and eleven (11) or more primary percutaneous coronary interventions per year. If an operator does not perform a recommended eleven (11) or more primary percutaneous coronary interventions per year, he or she shall have a mentoring relationship defined by written agreement with a highly experienced operator. This mentor may be a member of the same institution or belong to another institution. This relationship, established by a written agreement, may include, but not be limited to, on-site supervision and observation of performance during primary and elective percutaneous coronary interventions per year, review of mentee's patient encounters, review of mentee's outcomes, evaluation of mentee and hospital's process pertaining to elective and primary percutaneous coronary interventions, and guidance on methods to improve process, performance, and outcomes; or

B. If a STEMI center performs less than an annual recommended average of two hundred (200) elective percutaneous coronary interventions over three (3) consecutive preceding years, it is recommended that the STEMI center perform an annual average of thirty-six (36) primary percutaneous coronary interventions over three (3) consecutive preceding years, and it is recommended that all operators perform seventy-five (75) or more elective percutaneous coronary interventions and eleven (11) or more primary percutaneous coronary interventions per year or have a mentoring relationship defined by a written agreement with a highly experienced operator. This mentor may be a member of the same institution or belong to another institution. This relationship, established by a written agreement, may include, but not be limited to, on-site supervision and observation of performance during primary and elective percutaneous coronary interventions, review of mentee's patient encounters, review of mentee's outcomes, evaluation of mentee and hospital's process pertaining to elective and primary percutaneous coronary interventions, and guidance on methods to improve process, performance, and outcomes; and

C. Be able to provide on-site emergency cardiothoracic surgical services or have a written plan that has been shown to be effective, a transfer agreement, and expedited transfer process for cardiothoracic surgery back-up in a nearby STEMI center with appropriate hemodynamic support capability for transfer. The written plan shall ensure that once a potential need for cardiothoracic intervention is identified, the STEMI patient can be evaluated by cardiothoracic surgery and in the operating room of the receiving hospital as expeditiously as possible; and (II-R)

D. Provide cardiac intensive care capability; and (II-R)

E. Provide evidence of a written plan shown to be effective, a transfer agreement, and expedited transfer process for STEMI patients to higher level care in a nearby

STEMI center with appropriate hemodynamic support capability for transfer; and (II-R)

F. The STEMI center shall collect, document, maintain for at least five (5) years, and make available for review by the department the following:

(I) The STEMI center's average time from the STEMI center door to percutaneous coronary interventions device inflation time (i.e., door-to-balloon (D2B) times) is no more than ninety (90) minutes at least seventy-five percent (75%) of the time; and (II-R)

(II) The STEMI center tracks and compares the time from the first medical contact to balloon times; and (II-R)

G. The STEMI center shall document that it collects and trends its past and current risk-adjusted outcome and process measures. (II-R)

(G) The STEMI center shall appoint a physician to serve as the STEMI medical director with appropriate qualifications, experience, and training. A STEMI medical director shall be appointed at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. Level I and II STEMI center medical directors shall be cardiologists or interventional cardiologists. It is recommended that the cardiologist or interventional cardiologist be board-certified or board-admissible in interventional cardiology or cardiology. (I-R, II-R)

2. Level III and IV STEMI center medical directors shall be physicians. A board-certified or board-admissible physician is recommended. (III-R, IV-R)

3. The STEMI center shall have a job description and organization chart depicting the relationship between the STEMI medical director and other services. (I-R, II-R, III-R, IV-R)

4. Level I and II STEMI medical directors are recommended to be members of the catheterization lab team call roster. (I-R, II-R)

5. The STEMI medical director shall meet the continuing medical education (CME) requirements as described in section (4) of this rule. (I-R, II-R, III-R, IV-R)

6. The STEMI medical director shall be responsible for oversight of the education and training of the medical and clinical staff in STEMI care. This includes a review of the appropriateness of the education and training for the practitioner's level of responsibility. (I-R, II-R, III-R, IV-R)

7. Level I STEMI medical directors shall participate in the STEMI center's research and publication projects. (I-R)

(H) The STEMI center shall have a STEMI program coordinator/manager who is a registered nurse, other clinical staff, or qualified individual. The STEMI center shall have a STEMI program coordinator/manager at all times with no lapses. (I-R, II-R, III-R, IV-R)

1. The STEMI center shall have a job description and organization chart depicting the relationship between the STEMI program coordinator/manager and other services. (I-R, II-R, III-R, IV-R)

2. The STEMI coordinator/manager shall meet continuing education requirements as described in section (4) of this rule. (I-R, II-R, III-R, IV-R)

3. The STEMI program coordinator/manager shall participate in the formal STEMI center performance improvement and patient safety program. (I-R, II-R, III-R, IV-R)

(I) The STEMI center shall document a plan for and utilization of a specific and well-organized system as appropriate to center level designation for the emergency department to rapidly notify and activate the STEMI team or STEMI/cardiac catheterization lab team at the time the emergency department identifies STEMI on electrocardiogram (ECG) or verifies emergency medical services (EMS) STEMI electrocardiogram identification. (I-R, II-R, III-R, IV-R)

(J) The STEMI center shall have a protocol detailing a one- (1-) call cardiac catheterization lab activation by emergency medical services at the time emergency medical services identifies a STEMI patient and as appropriate to the hospital's process. (I-R, II-R)

(K) The STEMI center shall have a one- (1-) call STEMI team activation protocol or a STEMI/cardiac catheterization lab team activation protocol as appropriate for center level designation that establishes the following:

1. The criteria used to triage STEMI patients; (I-R, II-R, III-R, IV-R)

2. The person authorized to notify STEMI team or STEMI team/cardiac catheterization lab team members when a suspected STEMI patient is in route or when a suspected STEMI patient has arrived at the STEMI center; and (I-R, II-R, III-R, IV-R)

3. The method for immediate notification and the response requirements for STEMI team or STEMI/cardiac catheterization lab team members when a suspected STEMI patient is in route to the STEMI center. (I-R, II-R, III-R, IV-R).

(L) All members of the STEMI team or STEMI/cardiac catheterization lab team call roster shall comply with the availability and response requirements. If not on STEMI center premises, then STEMI/cardiac catheterization lab team members who are on call shall carry electronic communication devices at all times to permit contact by the STEMI center and shall be promptly available. (I-R, II-R, III-R, IV-R)

(M) The STEMI centers shall have a fibrinolysis protocol for instances when percutaneous coronary intervention is not achievable within an appropriate designated time frame and for when fibrinolysis is achievable within an appropriate designated time frame. It is recommended that the designated time frame follow nationally acceptable standards, for example as set forth in Appendix A number eight (8) entitled "Time to Fibrinolytic Therapy" included in the article entitled "ACC/AHA Clinical Performance Measures for Adults with ST-Elevation and Non-ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Performance Measures on ST-Elevation and Non-ST-Elevation Myocardial Infarction)" as published by the Journal of the American College of Cardiology in 2006, volume 47, pages 236–265 which is incorporated by reference in this rule and is available at the Journal of the American College of Cardiology, Reprint Department Elsevier Inc., 360 Park Avenue South, New York, NY 10010-1710 or on the Journal of the American College of Cardiology website at http://content.onlineJACC.org. This rule does not incorporate any subsequent amendments or additions. (I-R, II-R, III-R, IV-R)

(N) STEMI centers shall have transfer agreements between referring and receiving facilities. (II-R, III-R, IV-R)

1. The STEMI center shall have a one- (1-) call transfer protocol to a level I or level II designated STEMI center that establishes the criteria used to triage STEMI patients and identifies the persons authorized to notify the designated STEMI center. (II-R, III-R, IV-R)

2. The STEMI center shall have a rapid transfer process in place to transport a STEMI patient to a higher level of STEMI care when needed. (II-R, III-R, IV-R)

(O) STEMI centers shall have cardiac rehabilitation services directed by a physician experienced in cardiac rehabilitation. (I-R, II-R)

(P) The STEMI centers shall demonstrate that there is a plan for adequate post-discharge and post-transfer follow-up on STEMI patients, including cardiac rehabilitation and repatriation if indicated. (I-R, II-R, III-R, IV-R)

(Q) The STEMI center shall maintain a STEMI patient log, keep this log for a period of five (5) years, and make this log readily retrievable during a review by the department. This patient log shall include all

STEMI patients and shall contain the following information:

1. Response times; (I-R, II-R, III-R, IV-R)

2. Patient diagnosis; (I-R, II-R, III-R, IV-R)

3. Treatment/actions; (I-R, II-R, III-R, IV-R)

4. Outcomes; (I-R, II-R, III-R, IV-R)

5. Number of patients; and (I-R, II-R, III-R, IV-R)

6. Benchmark indicators. (I-R, II-R, III-R, IV-R)

(R) Level I, II, and III STEMI centers shall have a lighted designated helicopter landing area at the STEMI center to accommodate incoming medical helicopters. (I-R, II-R, III-R)

1. The landing area shall serve solely as the receiving and take-off area for medical helicopters and shall be cordoned off at all times from the general public to assure its continual availability and safe operation. (I-R, II-R, III-R)

2. The landing area shall be on the hospital premises no more than three (3) minutes from the emergency room. (I-R, II-R, III-R)

(S) Level IV STEMI centers shall have a lighted designated helicopter landing area that meets the following requirements:

1. Accommodates incoming medical helicopters; (IV-R)

2. Serves as the receiving and take-off area for medical helicopters; (IV-R)

3. Cordoned off from the general public when in use; (IV-R)

4. Managed to assure its continual availability and safe operation; and (IV-R)

5. It is recommended the landing area shall be no more than three (3) minutes from the emergency department. (IV-R)

(T) STEMI centers shall enter data into the Missouri STEMI registry as follows:

1. All STEMI centers shall submit data into the department's Missouri STEMI registry on each STEMI patient who is admitted to the STEMI center, transferred out of the STEMI center, or dies as a result of the STEMI (independent of hospital admission or hospital transfer status). The data required to be submitted into the Missouri STEMI registry by the STEMI centers is listed and explained in the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at www.health.mo.gov. This rule does not incorporate any subsequent amendments or additions; (I-R, II-R, III-R, IV-R)

2. The data required in paragraph (1)(T)1. above shall be submitted electronically into the Missouri STEMI registry via the department's website at www.health.mo.gov; (I-R, II-R, III-R, IV-R)

3. This data required in paragraph (1)(T)1. above shall be submitted electronically into the Missouri STEMI registry on at least a quarterly basis for that calendar year. STEMI centers have ninety (90) days after the quarter ends to submit the data electronically into the Missouri STEMI registry; (I-R, II-R, III-R, IV-R)

4. The data submitted by the STEMI centers shall be complete and current; and (I-R, II-R, III-R, IV-R)

5. The data submitted by the STEMI centers shall be managed in compliance with the confidentiality requirements and procedures contained in section 192.067, RSMo. (I-R, II-R, III-R, IV-R)

(U) A STEMI center shall maintain a diversion protocol for the STEMI center that is designed to allow best resource management within a given area. The STEMI center shall create criteria for diversion in this diversion protocol and shall detail a performance improvement and patient safety process in the diversion protocol to review and validate the criteria for diversion created by the STEMI center. The STEMI center shall also collect, document, and maintain diversion information that includes at least the date, length of time, and reason for diversion. This diversion information shall be readily retrievable by the STEMI center during a review by the department and shall be kept by the STEMI center for a period of five (5) years. (I-R, II-R, III-R, IV-R)

(2) Medical Staffing Standards for STEMI Center Designation.

(A) There shall be a delineation of privileges for the cardiologists, cardiothoracic surgeons, and interventional cardiologists made by the medical staff credentialing committee in each STEMI center. (I-R, II-R)

(B) The STEMI center shall credential and have different types of physicians available as listed below—

1. A cardiologist; (I-R/PA, II-R/PA)

2. An interventional cardiologist; (I-R/PA, II-R/PA)

3. A cardiothoracic surgeon as follows:

A. A cardiothoracic surgeon and back-up coverage shall be available for level I STEMI centers and for those level II STEMI centers which provide cardiothoracic surgery; or (I-R/PA, II-R/PA)

B. A cardiothoracic surgeon and back-up coverage arrangements with a level I STEMI center or a level II STEMI center which provides cardiothoracic surgery shall be available for those level II STEMI centers that do not provide cardiothoracic surgery to ensure that the STEMI patient is in the operating room of the receiving STEMI center as expeditiously as possible, recommended within sixty (60) minutes of the time surgery is determined needed; (II-R)

4. An emergency department physician; (I-R/IH, II-R/IH, III-R/IH, IV-R/IA)

5. An internal medicine physician; (I-R/PA, II-R/PA, III-R/PA)

6. A diagnostic radiologist; and (I-R/IA, II-R/IA, III-R/IA, IV-R/PA)

7. An anesthesiologist. (I-PA, II-PA)

A. Anesthesiology staffing requirements may be fulfilled by anesthesiology residents or certified registered nurse anesthetists (CRNA), or anesthesia assistants capable of assessing emergent situations in STEMI patients and of providing any indicated treatment including induction of anesthesia. When anesthesiology residents or CRNAs are used to fulfill availability requirements, the staff anesthesiologist on call will be advised and be promptly available and present for all operative interventions and emergency airway conditions. The CRNA may proceed with life preserving therapy while the anesthesiologist is in route under the direction of the cardiologist/cardiovascular surgeon, including induction of anesthesia. An anesthesiologist assistant shall practice only under the direct supervision of an anesthesiologist who is physically present or immediately available as this term is defined in section 334.400, RSMo. (I-PA, II-PA)

(3) Standards for Hospital Resources and Capabilities for STEMI Center Designation.

(A) The STEMI center shall meet emergency department standards listed below.

1. The emergency department staffing shall meet the following requirements:

A. The emergency department in the STEMI center shall provide immediate and appropriate care of the STEMI patient; (I-R, II-R, III-R, IV-R)

B. A level I STEMI center shall have a medical director of the emergency department who shall be a board-certified or board-admissible physician in emergency medicine by the American Board of Medical Specialties, the American Osteopathic Association Board of Osteopathic Specialists, or the Royal College of Physicians and Surgeons of Canada; (I-R)

C. A level II STEMI center shall have a medical director of the emergency department who shall be a board-certified or board-admissible physician; (II-R)

D. A level III and IV STEMI center shall have a medical director of the emergency department who is recommended to be a board-certified or board-admissible physician; (III-R, IV-R)

E. There shall be an emergency department physician credentialed for STEMI care covering the emergency department twenty-four (24) hours a day, seven (7) days a week; (I-R/IH, II-R/IH, III-R/IH, IV-R/IA)

F. The emergency department physician who provides coverage shall be current in continuing medical education (CME) in the area of cardiovascular disease as set forth in section (4) of this rule; (I-R, II-R, III-R, IV-R)

G. There shall be a written policy defining the organizational relationship of the emergency department physicians to other physician members of the STEMI team; (I-R, II-R, III-R, IV-R)

H. Registered nurses in the emergency department shall be current in continuing education requirements as set forth in section (4) of this rule; (I-R, II-R, III-R, IV-R)

I. At a minimum, all registered nurses assigned to the emergency department shall be determined to be credentialed in the care of the STEMI patient by the STEMI center within one (1) year of assignment in the emergency department, and these registered nurses shall remain current in continuing education requirements as set forth in section (4) of this rule; and (I-R, II-R, III-R, IV-R)

J. The emergency department in STEMI centers shall have written care protocols for identification, triage, and treatment of acute STEMI patients that are available to emergency department personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R, IV-R)

2. Nursing documentation for the STEMI patient shall be on a STEMI flow sheet approved by the STEMI medical director and the STEMI program manager/coordinator. (I-R, II-R, III-R, IV-R)

3. The emergency department shall have at least the following equipment for resuscitation and life support available to the unit:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes; (I-R, II-R, III-R, IV-R)

(II) Endotracheal tubes; (I-R, II-R, III-R, IV-R)

(III) Bag-mask resuscitator; (I-R, II-R, III-R, IV-R)

(IV) Sources of oxygen; and (I-R, II-R, III-R, IV-R)

(V) Mechanical ventilator; (I-R, II-R, III-R)

B. Suction devices; (I-R, II-R, III-R, IV-R)

C. Electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R, III-R, IV-R)

D. Central line insertion equipment; (I-R, II-R, III-R)

E. All standard intravenous fluids and administration devices including intravenous catheters and intraosseous devices; (I-R, II-R, III-R, IV-R)

F. Drugs and supplies necessary for STEMI emergency care; (I-R, II-R, III-R, IV-R)

G. Two- (2-) way communication link with emergency medical service (EMS) vehicles; (I-R, II-R, III-R, IV-R)

H. Equipment necessary to communicate with emergency medical services regarding pre-hospital ECG STEMI findings; (I-R, II-R, III-R, IV-R)

I. End-tidal carbon dioxide monitor; (I-R, II-R, III-R, IV-R)

J. Temperature control devices for patient and resuscitation fluids; (I-R, II-R, III-R, IV-R)

K. External pacemaker; and (I-R, II-R, III-R, IV-R)

L. Transvenous pacemaker. (I-R/IA, II-R/IA, III-R/IA)

4. The STEMI center emergency department shall maintain all equipment according to the hospital preventive maintenance schedule and document when the equipment is checked. (I-R, II-R, III-R, IV-R)

(B) The STEMI center shall have a designated intensive care unit (ICU). (I-R, II-R)

1. The STEMI center intensive care unit shall ensure staffing to provide appropriate care of the STEMI patient. (I-R, II-R)

A. The STEMI center intensive care unit shall have a designated medical director who has twenty-four (24) hours a day, seven (7) days a week access to a physician knowledgeable in STEMI care who meets the STEMI call roster continuing education requirements as set forth in section four (4) of this rule. (I-R, II-R)

B. The STEMI center intensive care unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week in the STEMI center who is not the emergency department physician. This physician shall have access to a physician on the STEMI call roster. (I-R, II-R)

C. The STEMI center intensive care unit shall have a one to one (1:1) or one to two (1:2) registered nurse/patient ratio used for critically ill patients requiring intensive care unit level care. (I-R, II-R)

D. Registered nurses in the STEMI center intensive care unit shall annually maintain core competencies in the care of the STEMI patient and remain current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R)

2. The STEMI center intensive care unit shall have written care protocols for identification and treatment of acute STEMI patients which are available to intensive care unit personnel, reviewed annually, and revised as needed. (I-R, II-R)

3. The STEMI center intensive care unit shall have intensive care unit beds for STEMI patients or, if space is not available in the intensive care unit, the STEMI center shall make arrangements to provide the comparable level of care until space is available in the intensive care unit. (I-R, II-R)

4. The STEMI center intensive care unit shall have equipment available for resuscitation and to provide life support for the STEMI patient. This equipment shall include at least the following:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes, bag-mask resuscitator, and a mechanical ventilator; (I-R, II-R)

B. Oxygen source with concentration controls; (I-R, II-R)

C. Cardiac emergency cart, including medications:

(I) External pacemaker; and (I-R, II-R)

(II) Transvenous pacemaker; (I-R, II-R)

D. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R)

E. Electronic pressure monitoring and pulse oximetry; (I-R, II-R)

F. End-tidal carbon dioxide monitor; (I-R, II-R)

G. Patient weighing devices; and (I-R, II-R)

H. Drugs, intravenous fluids, and supplies. (I-R, II-R)

5. The STEMI center intensive care unit shall check all equipment according to the hospital preventive maintenance schedule and document when it is checked. (I-R, II-R)

(C) The STEMI center shall have a cardiac catheterization lab. (I-R, II-R)

1. The STEMI center cardiac catheterization lab shall have angiography with interventional capability available twenty-four (24) hours a day, seven (7) days a week. (I-R/PA, II-R/PA)

2. All members of the STEMI center catheterization lab and team shall maintain core competencies annually as required by the STEMI center. (I-R, II-R)

3. Resuscitation equipment shall be readily available in the STEMI center catheterization lab. (I-R, II-R)

4. The following diagnostic equipment shall be readily available in the STEMI center cardiac catheterization lab:

A. Sheaths; (I-R, II-R)

B. Diagnostic wires; (I-R, II-R)

C. Diagnostic catheters; (I-R, II-R)

D. Manifold or contrast injector/delivery system; and (I-R, II-R)

E. Pressure tubing. (I-R, II-R)

5. The following interventional equipment shall be readily available in the STEMI center cardiac catheterization lab:

A. Sheaths; (I-R, II-R)

B. Interventional guide wires; (I-R, II-R)

C. Interventional guide catheters; (I-R, II-R)

D. Balloon catheters—

(I) Compliant; and (I-R, II-R)

(II) Non-compliant; (I-R, II-R)

E. Stents—

(I) Bare metal stents; and (I-R, II-R)

(II) Drug eluting stents; (I-R, II-R)

F. Balloon pump catheters; and (I-R, II-R)

G. Thrombectomy aspiration catheters or mechanical thrombectomy device. (I-R, II-R)

6. The following equipment shall be readily available to the STEMI center cardiac catheterization lab:

A. Balloon pump; (I-R, II-R)

B. The level I STEMI center cardiac catherization labs shall have percutaneous or surgically implanted circulatory assist devices (i.e., left ventricular assistive device (LVAD)). It is also recommended that the level II STEMI center cardiac catherization labs have left ventricular assistive devices; and (I-R)

C. Emboloic protection device. (I-R, II-R)

7. The cardiac catheterization laboratory shall maintain equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R, II-R)

(D) The STEMI center shall have an intermediate care unit (e.g., step down unit). (I-R, II-R, III-R)

1. The STEMI center shall have a designated medical director for the STEMI center intermediate care unit who has access to a physician knowledgeable in STEMI care and who meets the STEMI call roster continuing medical education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

2. The STEMI center intermediate care unit shall have a physician on duty or available twenty-four (24) hours a day, seven (7) days a week who is not the emergency department physician. This physician shall have access to a physician on the STEMI call roster. (I-R/IA, II-R/IA, III-R/IA)

3. The STEMI center intermediate care unit shall have registered nurses and other essential personnel on duty twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R, III-R)

4. The STEMI center intermediate care unit registered nurses shall remain current in continuing education requirements as set forth in section (4) of this rule. (I-R, II-R, III-R)

5. The STEMI centers shall annually credential registered nurses that work in the intermediate care unit. (I-R, II-R, III-R)

6. The STEMI center intermediate care unit shall have written care protocols for identification and treatment of STEMI patients which are available to the cardiac unit personnel, reviewed annually, and revised as needed. (I-R, II-R, III-R)

7. The STEMI center intermediate care unit shall have equipment to support the care and resuscitation of the STEMI patient that includes at least the following:

A. Airway control and ventilation equipment including:

(I) Laryngoscopes, endotracheal tubes of all sizes; (I-R, II-R, III-R)

(II) Bag-mask resuscitator and sources of oxygen; and (I-R, II-R, III-R)

(III) Suction devices; and (I-R, II-R, III-R)

B. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R, III-R)

C. All standard intravenous fluids and administration devices and intravenous catheters; and (I-R, II-R, III-R)

D. Drugs and supplies necessary for emergency care. (I-R, II-R, III-R)

8. The STEMI center intermediate care unit shall maintain equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R, II-R, III-R)

(E) The STEMI center shall have the following radiological and diagnostic capabilities:

1. The STEMI center radiological and diagnostic capabilities shall include a mechanism for timely interpretation to aid in the management of STEMI patients; (I-R, II-R, III-R, IV-R)

2. Resuscitation equipment shall be readily available in the radiology department; (I-R, II-R, III-R, IV-R)

3. The STEMI center radiology department shall have adequate physician and nursing personnel available with monitoring equipment to fully support the STEMI patient and provide documentation of care during the time the patient is physically present in the radiology department and during transportation to and from the radiology department; (I-R, II-R, III-R, IV-R)

4. The STEMI center radiology department shall have x-ray capability with twenty-four (24) hours a day, seven (7) days a week coverage; (I-R/IH, II-R/IH, III-R/IA, IV-R/PA)

5. The STEMI center radiology department shall have a radiological technician; (I-R/IH, II-R/IH, III-R/IA, IV-R/PA)

6. The STEMI center radiology department shall have in-house computerized tomography; (I-R, II-R)

7. The STEMI center radiology department shall have a computerized tomography technician; and (I-R/IH, II-R/IA)

8. The STEMI center shall maintain all radiology and diagnostic equipment according to the hospital's preventive maintenance schedule and document when the equipment is checked. (I-R, II-R, III-R, IV-R)

(F) All level I STEMI centers and level II STEMI centers with cardiothoracic surgery capability shall have operating room personnel, equipment, and procedures that meet the following requirements:

1. The STEMI center operating room staff shall be available twenty-four (24) hours a day, seven (7) days a week; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

2. Registered nurses in the STEMI center operating room shall maintain core competencies annually as required by the STEMI center; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

3. The STEMI center shall provide twenty-four (24) hours a day, seven (7) days a week heart team coverage. This heart team includes physicians, perfusionists, and qualified individuals on call and available to provide cardiothoracic surgery; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

4. The STEMI center operating rooms shall have at least the following equipment:

A. Thermal control equipment for patient and resuscitation fluids; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

B. X-ray capability; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

C. Instruments and equipment necessary for cardiothoracic surgical services; (I-R/PA, II-R/PA with cardiothoracic surgery capability)

D. Patient monitoring equipment; and (I-R/PA, II-R/PA with cardiothoracic surgery capability)

E. Resuscitation equipment readily available to the operating room; and (I-R/PA,

II-R/PA with cardiothoracic surgery capability)

5. The STEMI center operating room shall maintain all equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R/PA, II-R/PA with cardiothoracic surgery capability)

(G) All level I STEMI centers shall meet post-anesthesia recovery room (PAR) requirements as set out below. Those level II STEMI centers with cardiothoracic surgery capability shall also have a post-anesthesia recovery room and meet the requirements as set out below. (I-R/PA, II-R/PA with cardiothoracic surgery capability)

1. The STEMI center post-anesthesia recovery rooms shall have registered nurses and other essential personnel on call and available within sixty (60) minutes twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R with cardiothoracic surgery capability)

2. Registered nurses who work in the STEMI center post-anesthesia recovery room shall maintain core competencies annually as required by the STEMI center. (I-R, II-R with cardiothoracic surgery capability)

3. The STEMI center post-anesthesia recovery rooms shall have at least the following equipment for resuscitation and to provide life support for the STEMI patient:

A. Airway control and ventilation equipment including laryngoscopes, endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen, and mechanical ventilator; (I-R, II-R with cardiothoracic surgery capability)

B. Suction devices; (I-R, II-R with cardiothoracic surgery capability)

C. Telemetry, electrocardiograph, cardiac monitor, and defibrillator; (I-R, II-R with cardiothoracic surgery capability)

D. All standard intravenous fluids and administration devices, including intravenous catheters; and (I-R, II-R with cardiothoracic surgery capability)

4. Drugs and supplies necessary for emergency care. (I-R/PA, II-R/PA with cardiothoracic surgery capability)

5. The STEMI center post-anesthesia recovery room shall maintain all equipment according to the STEMI center's preventive maintenance schedule and document when the equipment is checked. (I-R, II-R with cardiothoracic surgery capability)

(H) The STEMI center shall have clinical laboratory services available twenty-four (24) hours a day, seven (7) days a week. (I-R, II-R, III-R, IV-R)

1. The STEMI center's clinical laboratory services shall have a written protocol to provide timely availability of results. (I-R, II-R, III-R, IV-R)

2. The STEMI center's clinical laboratory services shall be able to conduct standard analyses of blood, urine, and other body fluids. (I-R, II-R, III-R, IV-R)

3. The STEMI center's clinical laboratory services shall be able to conduct blood typing and cross-matching. (I-R, II-R, III-R)

4. The STEMI center's clinical laboratory services shall be able to conduct coagulation studies. (I-R, II-R, III-R, IV-R)

5. Clinical laboratory services at level I, II, and III STEMI centers shall include a comprehensive blood bank or access to a community central blood bank and adequate hospital blood storage facilities. (I-R, II-R, III-R)

6. Clinical laboratory services at level IV STEMI centers shall include a blood bank or access to a community central blood bank and adequate hospital blood storage facilities. (IV-R)

7. The STEMI center's clinical laboratory services shall be able to perform blood gases and pH determinations. (I-R, II-R, III-R, IV-R)

8. The STEMI center's clinical laboratory services shall be able to perform blood chemistries. (I-R, II-R, III-R, IV-R)

9. The STEMI center's clinical laboratory services shall have a written protocol for prioritization of the STEMI patient in comparison to other time critical patients. (I-R, II-R, III-R, IV-R)

(I) The STEMI center shall have support services to assist the STEMI patient's family from the time of entry into the facility to the time of discharge or transfer, and the support services that were provided shall be documented. (I-R, II-R, III-R, IV-R)

(J) The STEMI center shall have cardiac rehabilitation or a written network agreement for the provision of cardiac rehabilitation. (I-R, II-R, III-R)

1. Level I and level II STEMI centers shall have Phase I cardiac rehabilitation on site. (I-R, II-R)

(4) Continuing Medical Education (CME) and Continuing Education Standards for STEMI Center Designation.

(A) The STEMI center shall ensure that staff providing services to STEMI patients receive continued medical education and continuing education as set forth in section (4) of this rule and document this education for each staff member. The department shall allow up to one (1) year from the date of the STEMI center's initial STEMI center designation for STEMI center staff members to complete all of the required continuing medical education and/or continuing education requirements if the STEMI center staff documents that at least half of the required continuing medical education and continuing education hours have been completed for each STEMI center staff at the time of the on-site initial application review. The STEMI center shall submit documentation to the department within one (1) year of the initial designation date that all continued medical education and continuing education requirements for STEMI center staff members have been met in order to maintain the STEMI center's designation. (I-R, II-R, III-R, IV-R)

(B) The STEMI call roster members shall complete the following continuing education requirements:

1. Core team members of the STEMI call roster in level I and level II STEMI centers shall document a minimum of ten (10) hours every year of continuing education in the area of acute coronary syndrome. All other members of the STEMI call roster shall document a minimum of ten (10) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed by the STEMI center medical director for appropriateness to the practitioner's level of responsibility; and (I-R, II-R)

2. All members of the STEMI call roster in level III and level IV STEMI centers shall document a minimum of eight (8) hours every two (2) years of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed by the STEMI center medical director for appropriateness to the practitioner's level of responsibility. (III-R, IV-R)

(C) The STEMI center medical director shall complete the following continuing medical education requirements:

1. Level I and II STEMI medical directors shall document a minimum average of ten (10) hours every year in the area of acute coronary syndrome; (I-R, II-R)

2. The level III and IV STEMI medical directors that are board-certified or board-eligible shall document a minimum average of eight (8) hours every other year of continuing medical education in the area of cardiovascular disease; and (III-R, IV-R)

3. The level III and IV STEMI medical directors who are not board-certified or board-eligible shall document:

A. A minimum average of ten (10) hours every two (2) years of continuing medical education in the area of cardiovascular disease with a focus on acute coronary syndrome; and (III-R, IV-R)

B. Attend one (1) national, regional, or state meeting every three (3) years in cardiovascular disease. Continuing medical education earned at these meetings can count toward the ten (10) continuing medical education hours required. (III-R, IV-R)

(D) The STEMI center's STEMI program manager/coordinator shall complete the following continuing education requirements:

1. A level I STEMI program coordinator/manager shall complete and document the following:

A. A minimum average of ten (10) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the STEMI program manager's/coordinator's level of responsibility; and (I-R)

B. Attend one (1) national, regional, or state meeting every two (2) years focused on cardiovascular disease. If the national, regional, or state meeting provides continuing education, that continuing education may count towards the annual requirement; (I-R)

2. A level II STEMI program coordinator/manager shall complete and document the following:

A. A minimum average of eight (8) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed by the STEMI center medical director for appropriateness to the STEMI program manager's/coordinator's level of responsibility; and (II-R)

B. Attend one (1) national, regional, or state meeting every three (3) years focused on cardiovascular disease. If the national, regional, or state meeting provides continuing education, that continuing education may count toward the annual requirement; and (II-R)

3. The level III and IV STEMI program coordinator/manager shall complete and document a minimum average of eight (8) hours every other year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the STEMI program manager's/coordinator's level of responsibility. (III-R, IV-R)

(E) STEMI center emergency department personnel shall complete the continuing education requirements for STEMI centers that are detailed below.

1. The emergency department physician(s) shall be current in cardiovascular continuing medical education. (I-R, II-R, III-R, IV-R)

A. Emergency department physicians in level I and II STEMI centers shall complete and document a minimum average of four (4) hours every year of continuing medical education in the area of cardiovascular disease. (I-R, II-R)

B. Emergency department physicians in level III and IV STEMI centers shall complete and document a minimum average of six (6) hours every two (2) years of continuing medical education in the area of cardiovascular disease. (III-R, IV-R)

2. Registered nurses assigned to the emergency department shall complete the following requirements:

A. Registered nurses assigned to the emergency department at level I and II STEMI centers shall complete and document a minimum of four (4) hours of continuing education every year in the area of cardiovascular disease; (I-R, II-R)

B. Registered nurses assigned to the emergency department at level III and IV STEMI centers shall complete and document a minimum of six (6) hours of continuing education every two (2) years in the area of cardiovascular disease; and (III-R, IV-R)

C. Registered nurses assigned to the emergency department at STEMI centers shall maintain core competencies in the care of the STEMI patient annually as determined by the STEMI center. Continuing education earned in training to maintain these competencies may count toward continuing education requirements. (I-R, II-R, III-R, IV-R)

(F) Registered nurses assigned to the intensive care unit who provide care to STEMI patients shall complete the following continuing education requirements:

1. Registered nurses in the intensive care unit shall complete and document a minimum of eight (8) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility. (I-R, II-R).

(G) Registered nurses and clinical staff assigned to the cardiac catheterization lab shall complete the following continuing education requirements:

1. Registered nurses and clinical staff shall complete and document a minimum of eight (8) hours of continuing education every year in the area of acute coronary syndrome. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility. (I-R, II-R)

(H) Registered nurses assigned to the intermediate care unit shall complete the following continuing education requirements:

1. Intermediate care unit registered nurses in level I and level II STEMI centers shall complete and document a minimum of eight (8) hours every year of continuing education in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility; and (I-R, II-R)

2. Intermediate care unit registered nurses in level III STEMI centers shall complete and document a minimum of eight (8) hours of continuing education every two (2) years in the area of cardiovascular disease. This continuing education shall be reviewed for appropriateness by the STEMI center medical director to the practitioner's level of responsibility. (III-R)

(5) Standards for Hospital Performance Improvement, Patient Safety, Outreach, Public Education, and Training Programs for STEMI Center Designation.

(A) The STEMI center shall maintain an ongoing performance improvement and patient safety program designed to objectively and systematically monitor, review, and evaluate the quality, timeliness, and appropriateness of patient care, to resolve problems, and to improve patient care. (I-R, II-R, III-R, IV-R)

1. The STEMI center shall collect, document, trend, maintain for at least five (5) years, and make available for review by the department at least the following data elements:

A. Any STEMI center that performs percutaneous coronary interventions shall report all percutaneous coronary intervention-related data, including the time from first medical contact or pre-hospital electrocardiogram STEMI identification to hospital door time and the time from first medical contact to balloon or device time. The percutaneous coronary intervention-related data is set forth and identified in the columns labeled "Level I & II STEMI Centers" and "Only for Level III STEMI Centers which are Performing Percutaneous Coronary Interventions (PCIs) (Only on Patients Receiving Percutaneous Coronary Interventions (PCIs))" in the document entitled "Time Critical Diagnosis ST-Segment Elevation Myocardial Infarction (STEMI) Center Registry Data Elements" dated March 1, 2012, which is incorporated by reference in this rule and is available at the Missouri Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570 or on the department's website at www.health.mo.gov. This rule does not incorporate any subsequent amendments or additions; (I-R, II-R, III-R)

B. Thrombolytic administration time which is the time from first medical contact or pre-hospital electrocardiogram STEMI identification to hospital door time and the time from hospital door to needle time; (I-R, II-R, III-R, IV-R)

C. Number of STEMI patients presenting within the treatment window for percutaneous coronary interventions and/or thrombolytic administration; (I-R, II-R, III-R, IV-R)

D. Number of eligible STEMI patients treated with percutaneous coronary intervention and/or thrombolytic administration; and (I-R, II-R, III-R, IV-R)

E. Time from when STEMI patient presents at the receiving STEMI center to time STEMI patient is in the operating room at the receiving STEMI center. (I-R, II-R if cardiac surgical capability)

2. The STEMI center shall at least quarterly conduct a regular morbidity and mortality review. (I-R, II-R, III-R, IV-R)

3. The STEMI center shall conduct a review of the reports generated by the department from the Missouri STEMI registry. (I-R, II-R, III-R, IV-R)

4. The STEMI center shall conduct a monthly review of its pre-hospital STEMI care including inter-facility transfers. (I-R, II-R, III-R, IV-R)

5. The STEMI center shall participate in the emergency medical services regional system of STEMI care. (I-R, II-R, III-R, IV-R)

6. The STEMI center shall review cases of STEMI patients remaining greater than thirty (30) minutes at the referring hospital prior to transfer as a part of its performance improvement and patient safety program. (I-R, II-R, III-R, IV-R)

7. The STEMI center shall review and monitor the core competencies of its physicians, practitioners, and nurses. (I-R, II-R, III-R, IV-R)

(B) It is recommended that level I and II STEMI centers establish a cardiology outreach program that provides physicians in the outlying areas with telephone access to the cardiology program. (I-R, II-R)

(C) STEMI centers shall establish a patient and public education program to promote STEMI prevention and awareness of signs and symptoms. (I-R, II-R, III-R, IV-R)

(D) Level I, II, and III STEMI centers shall establish a professional education outreach program in catchment areas to provide training and other supports to improve care of STEMI patients. (I-R, II-R, III-R)

(E) Each STEMI center shall establish a training program on caring for STEMI patients for professionals in the STEMI center that includes at least the following:

1. A procedure for training nurses and clinical staff to be credentialed in STEMI care; (I-R, II-R, III-R, IV-R)

2. A mechanism to assure that all nurses providing care to STEMI patients complete a minimum of required continuing education to become credentialed in STEMI care; and (I-R, II-R, III-R, IV-R)

3. The content and format of any STEMI continuing education courses developed and offered by the STEMI center shall be developed with the oversight of the STEMI center medical director. (I-R, II-R, II-R, IV-R)

(F) STEMI centers shall provide and monitor timely feedback to the emergency medical services providers and referring hospital(s), if involved. This feedback shall include, at least, diagnosis, treatment, and referring hospital, if involved. It is recommended that the feedback be provided within seventy-two (72) hours of admission to the hospital. When emergency medical services does not provide patient care data on patient arrival or in a timely fashion (recommended within three (3) hours of patient delivery), this time frame shall not apply. (I-R, II-R, III-R, IV-R)

(G) The STEMI centers shall be actively involved in local and regional emergency medical services systems by providing training and clinical educational resources. (I-R, II-R, III-R, IV-R)

(6) Standards for the Programs in STEMI Research for STEMI Center Designation.

(A) The STEMI center and its staff shall support an ongoing research program in STEMI as evidenced by any of the following:

1. Production of evidence based reviews of the STEMI program's process and clinical outcomes; (I-R)

2. Publications in peer-reviewed journals; (I-R)

3. Reports of findings presented at regional or national meetings; (I-R)

4. Receipt of grants for study of STEMI care; (I-R)

5. Participation in multi-center studies; or (I-R)

6. Epidemiological studies and individual case studies. (I-R)

(B) The STEMI center shall agree to cooperate and participate with the department for the purpose of developing prevention programs. (I-R, II-R, III-R, IV-R)

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.770 Community-based or Regional Plan for Emergency Medical Services for Trauma, ST-Segment Elevation Myocardial Infarction (STEMI), or Stroke

PURPOSE: This rule establishes the procedures for the submission of a community-based or regional plan for the transportation of patients to stroke, STEMI, or trauma centers.

(1) A community or region developing its own transportation plan for stroke, STEMI, and trauma patients may submit a plan at any time and shall ensure that it complies with section 190.200.3, RSMo. Such a plan shall also—

(A) Identify the geographic boundaries of the area covered by the plan;

(B) Designate, and provide contact information for, an individual, plan's designee who will serve as the plan's point of contact throughout the plan's approval and administration process; and

(C) Identify individuals involved in the drafting, planning, and/or consultation of the plan, who shall collectively be known as the "planning committee."

(2) Upon completion of a community-based or regional plan, the plan shall be submitted to the chair of the regional emergency medical services advisory committee defined by section 190.102, RSMo, and the regional emergency medical services medical director defined by section 190.103, RSMo, for the geographic area covered by the plan. Upon receipt of a plan submitted pursuant to the provisions of section 190.200, RSMo, the chair and medical director shall forward the plan to the emergency medical services medical director's advisory committee (the committee) as defined by section 190.103, RSMo, for consideration. Within forty-five (45) days of receipt of a community-based or regional plan, the committee shall meet and complete its review of the plan. Upon a finding of good cause, the chair of the committee may grant the committee a reasonable extension of time for review of the plan.

(3) In reviewing a community-based or regional plan, the committee shall determine whether the plan meets the requirements of section 190.200.3, RSMo, and this rule.

(4) At the conclusion of its review, the committee shall vote on the question of whether

to recommend or not recommend the plan for approval. If a majority of the committee votes to recommend the plan for approval, said recommendation shall constitute *prima facie* evidence that the plan meets the requirements of section 190.200.3, RSMo, and should be approved. The committee shall attach such conditions (such as regular analysis and reporting of medical outcomes to the committee) to its recommendation for approval as it deems appropriate to ensure that the plan continues to meet the requirements of Chapter 190, RSMo. If a majority of the committee votes to not recommend the plan, that decision, with an explanation of the reason(s) for the decision, shall be provided in writing to the plan's designee. A community or region receiving a non-recommendation by the committee may modify its plan according to the committee's reason(s) for non-recommendation and resubmit the plan within thirty (30) days directly to the committee.

(5) Following recommendation of a community-based or regional plan, the committee shall forward the plan to the Director of the Department of Health and Senior Services (director) for approval. The director shall have thirty (30) days to review the plan for its compliance with section 190.200.3, RSMo. At the conclusion of the review, the director shall approve or disapprove the plan. If the director disapproves the plan, the reason(s) for disapproval shall be provided in writing to the plan's designee along with the right to appeal the director's decision. The director's decision shall be the final agency action. A community or region whose plan is not approved by the director may modify its plan according to the director's reason(s) for disapproval and resubmit the plan within thirty (30) days directly to the committee and follow the approval process as outlined herein.

(6) Once a plan is approved by the director, the planning committee shall—

(A) Notify all agencies impacted by the plan of the manner in which emergency medical care is modified within the region based on the plan;

(B) Monitor per the plan the related medical and system outcomes and regional resources and capacity;

(C) Revise the plan when indicated based on medical and system outcomes, emerging clinical research or guidelines, or when revision is indicated based on changes in capacity or other related issues and submit through the approval process as outlined herein; and

(D) Notify the committee and department at least thirty (30) days before ceasing to use the plan.

AUTHORITY: section 192.006, RSMo 2000, and sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 192.006, RSMo 1993, amended 1995; 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002; and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.780 Definitions and Abbreviations Relating to the Transport Protocol for Stroke and the Transport Protocol for ST-Segment Elevation Myocardial Infarction (STEMI) Patients

PURPOSE: This rule defines terminology related to the state transport protocol for stroke and the state transport protocol for STEMI.

(1) The following definitions and abbreviations shall be used in the interpretation of the rule in 19 CSR 30-40.790:

(A) Field is the specific area or location, outside of the hospital, where an injury, accident, or medical emergency occurs requiring immediate assistance of medical personnel for the purpose of treating or transporting the sick or injured to another location for treatment;

(B) Local and regional process is the process that has been established and agreed upon specifically pertaining to a local city, town, or small district, or a combination of localities forming a regional area. This is not the community-based or regional plan;

(C) Lytics are thrombolytic drugs, including recombinant tissue plasminogen activator, used to dissolve clots blocking flow in a blood vessel. These lytic/thrombolytic drugs are used in the treatment of acute ischemic stroke and acute myocardial infarction;

(D) Lytic/therapeutic window is the period of time during which lytics can be administered following the onset of symptoms in order to reduce brain or heart injury;

(E) Lytic therapy (fibrinolysis/thrombolysis) is drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction;

(F) Lytic/thrombolytic ineligible patients are those patients identified as ineligible for lytic/thrombolytic therapy due to specific contraindications. An appropriate course of treatment will be utilized when lytic/thrombolytic therapy is contraindicated;

(G) Out of the lytic/therapeutic or potential therapeutic window is the period of time following the accepted time (lytic/therapeutic window and potential therapeutic window) frames for specific therapies for a patient suffering an ischemic stroke;

(H) Outside of the percutaneous coronary intervention (PCI) window is the period of time following the accepted time frame in which PCI is most advantageous and recommended;

(I) Percutaneous coronary intervention (PCI) is a procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart;

(J) Percutaneous coronary intervention (PCI) window is a time frame in which PCI is most advantageous and recommended;

(K) Potential therapeutic window is the period of time after the accepted window for lytic therapy has expired in which interventional therapy may be beneficial in restoring blood flow during an ischemic stroke; and

(L) Recombinant tissue plasminogen activator (t-PA also known as rt-PA) is a thrombolytic (clot-dissolving) agent, the goal of which is to destroy the thrombus (clot) within the blood vessel by stimulating fibrinolysis (clot breakdown) to allow restoration of blood flow.

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987, amended 1998, 2008.*

19 CSR 30-40.790 Transport Protocol for Stroke and ST-Segment Elevation Myocardial Infarction (STEMI) Patients

PURPOSE: This rule establishes protocols for transporting suspected STEMI patients by severity and time of onset to the STEMI center where resources exist to provide appropriate care and suspected stroke patients by severity and time of onset to the stroke center where resources exist to provide appropriate care.

(1) All ground and air ambulances shall use the following state transport protocol for suspected stroke patients except in those circumstances listed in sections (3), (4), and (5) of this rule:

(A) Step 1—Assess for life threatening conditions (serious airway or respiratory compromise or immediate life threatening conditions that cannot be managed in the field).

1. If there are life threatening conditions, transport the patient to the nearest appropriate facility for stabilization prior to transport to a stroke center. Consider air/ground/facility options for timely and medically appropriate care (particularly in non-urban areas).

2. If there are no life threatening conditions, go to step 2 below in subsection (1)(B); and

(B) Step 2—Assess the duration of onset of symptoms (time last known well).

1. Group 1—If the patient is within the lytic/therapeutic window then transport to a level I, II, or III stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes, then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

2. Group 2—If the patient is within the potential therapeutic window then transport to a level I stroke center or transport to a level I, II, or III stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

3. Group 3—If the patient is out of the lytic/therapeutic and potential therapeutic windows, then transport to a level I, II, III, or IV stroke center according to local and regional process. Consider the time for transport, the patient's condition, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), and the treatment windows. Continue to reassess the patient. If the patient's condition changes, then start back with subsection (1)(A) and follow the state stroke protocol outlined in section (1) starting from subsection (1)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

(2) All ground and air ambulances shall use the following state transport protocol for suspected STEMI patients except in those circumstances listed in sections (3), (4), and (5) of this rule:

(A) Step 1—Assess for life threatening conditions (serious airway or respiratory compromise or immediate life threatening conditions that cannot be managed in the field).

1. If there are life threatening conditions, then transport the patient to the nearest appropriate facility for stabilization prior to transport to a STEMI center. Consider air/ground/facility options for timely and medically appropriate care (particularly in non-urban areas).

2. If there are no life threatening conditions, then go on to step 2 below in subsection (2)(B) and assess vital signs and perform an electrocardiogram (ECG) if the ground or air ambulance has that capability. An electrocardiogram and electrocardiogram equipment are recommended;

(B) Step 2—Determine if the patient's vital signs and the electrocardiogram identifies the following:

1. ST-elevation in two (2) contiguous leads or new or presumed new left bundle branch block; and

2. The patient has two (2) of the following three (3) signs of cardiogenic shock:

A. Hypotension where systolic blood pressure is less than ninety millimeters of mercury (90 mmHG);

B. Respiratory distress where respirations are less than ten (10) or greater than twenty-nine (29) per minute; or

C. Tachycardia where the heart rate is greater than one hundred beats per minute (100 BPM);

3. If the patient has an electrocardiogram with ST-elevation in two (2) contiguous leads or new or presumed new left bundle branch block and two (2) of the three (3) signs of cardiogenic shock then transport to a level I STEMI center according to local and regional process. Consider the time for transport, the patient's condition, and the air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas);

4. If initial transport from the scene to a level I STEMI center is prolonged, then consider transporting to the nearest appropriate facility for stabilization prior to transport to a level I STEMI center;

5. Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) above and follow the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition;

6. Consider out-of-state transport based on local and regional process for the bi-state region;

7. Communicate electrocardiogram findings to the hospital;

8. If the patient has a positive electrocardiogram but is negative for signs of cardiogenic shock, then go to step 3 in subsection (2)(C) below; and

(C) Step 3—Calculate the estimated time from STEMI identification with the patient to expected percutaneous coronary intervention (PCI) with the patient in order to determine whether the patient is within the percutaneous cornary intervention window. Communicate electrocardiogram findings to the hospital. If no ST-elevation or new or presumed new left bundle branch block then consider a fifteen-(15-) lead electrocardiogram, if available.

1. Group 1—If the patient is within the PCI window or the patient has had chest pain longer than twelve (12) hours or the patient is lytic/thrombolytic ineligible then transport to a level I or level II STEMI center according to local and regional process. Consider the time for transport, the air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), the patient's condition, and all treatment windows. Consider the ischemic time and the potential role for lytics (within the lytic window) at an intervening STEMI center in route to the percutaneous coronary intervention center if approaching longer times within the percutaneous coronary intervention window. Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) and follow the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

2. Group 2—If the patient is outside the percutaneous coronary intervention window and within the lytic/therapeutic window, or outside both windows and the patient has no other known complications, then transport to the STEMI center (level I, II, III, or IV) according to local and regional process. Consider the time for transport, air/ground/hospital options for timely and medically appropriate care (particularly in non-urban areas), the patient's condition, and all the treatment windows. Consider the lytic window and the potential for STEMI center lytic administration when determining the destination(s). Continue to reassess the patient. If the patient's condition changes, then start back at subsection (2)(A) above and follow

the state STEMI protocol outlined in section (2) starting from subsection (2)(A) and on according to the patient's condition. Consider out-of-state transport based on local and regional process for bi-state regions.

(3) When initial transport from the scene of illness or injury to a STEMI or stroke center would be prolonged, the STEMI or stroke patient may be transported to the nearest appropriate facility for stabilization prior to transport to a STEMI or stroke center.

(4) Nothing in this rule shall restrict an individual patient's right to refuse transport to a recommended destination. All ground and air ambulances shall have a written process in place to address patient competency and refusal of transport to the recommended destination.

(5) Ground and air ambulances are not required to use the state transport protocols in this rule when the ambulance is using a community-based or regional plan that has been approved by the department pursuant to section 190.200.3, RSMo, that waives the requirements of this rule. Copies of flow charts of an algorithm depicting the stroke and STEMI state transport protocols are available at the Health Standards and Licensure (HSL) office, online at the department's website www.health.mo.gov, or may be obtained by mailing a written request to the Missouri Department of Health and Senior Services, HSL, PO Box 570, Jefferson City, MO 65102-0570 or by calling (573) 751-6400.

AUTHORITY: sections 190.185 and 190.241, RSMo Supp. 2012. Original rule filed Nov. 15, 2012, effective June 30, 2013.*

**Original authority: 190.185, RSMo 1973, amended 1989, 1993, 1995, 1998, 2002 and 190.241, RSMo 1987, amended 1998, 2008.*